

TRILLIUM II

Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary

WP5

D5.1 v2019-08-02 Recommendations for the EU/US eHealth interoperability
roadmap:
Open Innovation in digital Health: the case of the international patient summary-
WP5-HL7

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Publishable summary:	<p>This deliverable consolidates reports on activities carried out under task 5.1 (EU/US eHealth Interoperability Roadmap), 5.2 (Stimulate engagement in standardization with open innovation), and in part 5.4 (Contribute feedback from implementation to align Patient Summary Standards sets in SDOs), contributing to recommendations on the progress of the EU/US Interoperability roadmap based on experience gained in the activities of the project.</p> <p>The report reflects on experience gained in efforts to stimulate engagement in standardization through open innovation activities. These activities promote cooperation among organizations and individuals that contribute to ongoing digital health initiatives in Europe, the United States and globally, and engaging or linking them to the work of Standards Development Organizations (SDOs) on patient summaries. Its focus is cross-fertilization among electronic patient summary initiatives in Europe, the United States and globally to enable patient empowerment. In this context, programs of relevance were the SEQUOIA project, Blue Button, Argonaut (US Core), Joint Action on Vaccination, CEF eHealth Digital Services Infrastructure, and eHaction. Additionally, initiatives such as HL7 FHIR Connectathons, and MIE DataThon, as well as a Hacking health program were explored as vehicles to open innovation. We also reach out to the participants in various SDO-led projects, including the European patient summary project led by CEN, the HL7 IPS project, HL7 FHIR resources for patient summaries, the CEN IPS project, and other relevant activities. Particular note was taken of the efforts of the WEF clinical value-based care initiative and Progressive project, which strives to engage user communities in standards development, maintenance, and adoption of standards for active and healthy aging.</p>				
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Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both. In case of policy documents or recommendations, as for example several sections in section 4, this is indicated by the preamble and citations.

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Deliverable Overview

Objectives

The objectives of Trillium II WP5 based on the description of Action are as follows:

- Contribute to a governance framework and processes for ensuring effective and efficient use and maintenance of patient summary specifications, in conjunction with the Joint Initiative Council (JIC) for global SDO health informatics standardization;
- Develop principles for deployment, incremental refinement and broad adoption of IPS and inform updates to the EU/ US roadmap;
- Inform the revision of European Patient Summary and other relevant Guidelines;
- Promote consensus and quality assured mappings of information structures and their value sets;
- Deliver feedback from implementation to SDOs from validation of information content structures and associated value sets to improve standards as needed.

Content

From the perspective of open innovation in digital health, considering the IPS as a case study, D5.1 addresses all objectives of WP5. However, IPS governance issues, feedback and recommendations to SDOs are predominately the main topics of D5.2. Trillium II D5.1 looks at the IPS as a case study for open innovation in digital health in the wider context of the EU/US eHealth interoperability roadmap (see section 3 and appendix). With this premise, D5.1 examines several initiatives that Trillium II engaged with and presents the implications (short conclusions in each subsection 4.x) and a small number of recommendations (section 8) for future revisions of the EU/US MoU roadmap. Trillium has promoted cooperation among organizations that contribute to ongoing digital health initiatives in Europe, the United States and globally, in a consistent effort to engage their participants in standards work related to the IPS. The role of open innovation in the engagement of stakeholders and in particular user communities in standards development, maintenance, and adoption was encouraged. With this backdrop, D5.1 examines how to further engage in standardization with open innovation, presenting several initiatives that Trillium instigated or participated in: MIE2018 DataThon, various IHE and FHIR Connectathons, as well as Hacking Health Athens (section 5). Keystone initiatives such as SEQUOIA project, Blue Button, Argonaut, and the CEF eHealth Digital Services Infrastructure as well as large scale European projects such as FrailSafe, C3Cloud, and EUMFH distilled the commentary of this deliverable, as we made efforts to ensure the effective and efficient use of global IPS standards and associated tools over time. We also reach out to the participants in various SDO-led projects, including project led by CEN and HL7 on the IPS, alignment with HL7 FHIR resources for Patient Care, the JIC PSSS standards set linked also to the Reference Standards Portfolio initiatives at ISO/TC215 (Section 6).

Deviations

There are deviations from the Description of Action (DoA). While in the DoA, Robert Stegwee (NEN) and Catherine Chronaki (HL7) were listed as the respective editors of D5.1 and D5.2, following decision of the Trillium II Project Executive Committee in the meeting on November 29, 2018, HL7 lead tasks T5.1 and T5.2 and Catherine Chronaki editor of D5.1 (r2) and Robert Stegwee (CEN lead of T5.3 and T5.4 and editor of D5.2. LISPA facilitated connections with the CEF eHealth DSI. SPMS organized WP5 workshop. Jeremy Thorp retired from NHS in 2018. IHE focused on IHE Connectathons and CDISC on the relation of IPS with CDASH (regulatory submissions). The Sequoia project provided background information for testing and certification in the USA. Early work on this deliverable has been presented to the JIC and comments were received. AHIMA provided input in early versions of the work feeding into this deliverable.

v2019-05-08 was replaced by v2019-08-02 in order to update on recent EU/US and global developments.

1 Executive summary

This deliverable consolidates reports on activities carried out under task 5.1 (EU/US eHealth Interoperability Roadmap), task 5.2 (Stimulate engagement in standardization with open innovation), and in part, task 5.4 (Contribute feedback from implementation to align Patient Summary Standards sets in SDOs), contributing to recommendations on the progress of the EU/US Interoperability roadmap based on experience gained in the activities of the project.

The report reflects on experience gained in efforts to stimulate engagement in standardization through open innovation activities. These activities promote cooperation among organizations and individuals that contribute to ongoing digital health initiatives in Europe, the United States and globally, and engaging or linking them to the work of Standards Development Organizations (SDOs) on patient summaries. It focusses on cross-fertilization to enable patient empowerment among electronic patient summary initiatives in Europe, the United States and globally. In this context, programs of relevance were the SEQUOIA project, Blue Button, Argonaut (US Core), Joint Action on Vaccination, CEF eHealth Digital Services Infrastructure, and eHaction. Additionally, initiatives such as HL7 FHIR Connectathons, and MIE Datathon, as well as a Hacking health program were explored as vehicles to open innovation. We also reached out to the participants in various SDO-led projects, including the European patient summary project led by CEN, the HL7 IPS project, HL7 FHIR resources for patient summaries, the CEN IPS project, and other relevant activities. Particular note was taken of the efforts of the WEF clinical value-based care initiative and Progressive project, which strives to engage user communities in standards development, maintenance, and adoption of standards for active and healthy aging.

2 Transatlantic eHealth/Health IT Cooperation Roadmap

The MoU between the United States Department of Health and Human Services and the European Commission, on Cooperation Surrounding Health Related Information and Communication Technologies (HHS-EC MOU) was signed in December 2010. Its main goal has been to promote individual and community health in a global environment.

The European Union and the United States have recognized Health related information and communication technology (frequently referenced as “eHealth” and “Health IT” respectively) as a rapidly developing area of high innovation potential particularly for the delivery of health services, including disease prevention and health promotion. Meanwhile, the Transatlantic Economic Council has decided to promote interoperability of eHealth/Health IT products and services, consistent proficiency recognition of the professional workforce, while helping prevent unnecessary regulatory divergences.

Key to the implementation of the MoU was to enable a robust and innovative global eHealth/Health IT ecosystem. This ecosystem would support the electronic exchange of human- and machine-readable health, clinical, medical and management information to advance the health of individuals and communities. Inter-governmental cooperation and also collaboration between governments and the private sector would maintain and enhance this ecosystem through specific activities and approaches to implementing transatlantic and global interoperability. Concrete steps and activities were specified in three editions of the HHS-EU MoU roadmap^{1,2,3} and associated action plans.

2.1 HHS-EU MoU Roadmap 2016 edition

The Vision of the Transatlantic eHealth/Health IT Cooperation Roadmap third revision in 2016 has been:

To support an innovative, collaborative community of public- and private-sector entities, including suppliers of eHealth solutions, working toward the shared objective of developing, deploying, and using eHealth science and technology to empower individuals, support care, improve clinical outcomes, enhance patient safety and improve the health of populations.

This Roadmap and Action Plan in its Annex place specific emphasis on three priority areas identified as having immediate importance and potential, with the first and the third being more closely linked to the Trillium II workplan:

1. International interoperability among Health IT systems with patient summary records, including a focus on semantic and syntactic requirements (including identification, privacy and security issues surrounding exchange of health data) for the purposes of clinical care across borders;

The first phase of the collaboration (www.trilliumbridge.eu) led to a successful comparison of patient summary specifications across EU and US. This activity mobilised resources across the Atlantic to identify gaps and assemble interoperability assets to help bridge those gaps. Detailed analyses of clinical and administrative components of patient summary documents used in the EU and US led to:

- a. EU/US demonstrations of provider and patient mediated scenarios in 2014-5 that provided evidence to the potential of transatlantic and global exchange of patient summaries

¹ <https://ec.europa.eu/digital-single-market/en/transatlantic-cooperation>

² http://ec.europa.eu/information_society/newsroom/image/document/2016-30/eu_us_roadmap_16674.pdf

³ <https://www.state.gov/p/eur/rls/or/2016/260928.htm>

- b. Progress towards widespread deployment and routine use of internationally recognized standards is an essential element of cooperation
- c. Agreement of EU and US counterparts to advance an IPS standard for people to access and share their health information for planned or emergency care anywhere and as needed
- d. Joint work on the design of an International Patient Summary (IPS) document standard to facilitate cross-border exchange of health data.

The action plan associated with the 2016 Roadmap included many of the Trillium Bridge Recommendations on international interoperability and concerned new activities and use cases that empower patients to use their IPS and recognized the importance of developments such as software designed for mobile and medical devices and. This is done in addition to advancing standardization with projects such as the CEN/IPS project and the HL7 CDA and HL7 FHIR IPS projects. The concrete actions and progress made is presented in the next section.

- 2. eHealth/Health IT Workforce Development – Cooperation and collaboration around shared challenges related to eHealth/Health IT Workforce Development. In May 2015, the eHealth/Health IT Workforce Development work-stream, identified competency and knowledge deficiencies among eHealth/Health IT professionals. The next phase involves EU and US eHealth/Health IT professionals & organizations working towards developing a global workforce for eHealth/Health IT systems;
- 3. Supporting Transatlantic eHealth/Health IT Innovation Ecosystems which is closely linked to the objective of creating a global digital health innovation community through the use of the IPS.

Public, academic and private-sector stakeholders from the EU and U.S. were invited to participate in these work-streams. Public sector participants were expected to stimulate and support creative collaborations amongst capable and willing private sector and academic participants, while offering policy making guidance. Participants were invited to identify solutions consistent with best practices in relevant fields (such as health informatics, workforce development, and IT-based innovation in healthcare systems). With respect to the implementation of standards, the workplan of the Trillium II project supported these activities with the Global Community of Practice for digital health innovation.

2.1.1 Action plan for the implementation of the HHS-EU MoU Roadmap 2016

Four key actions are recognized in the international interoperability workstream for Standards and Profile Developing Organizations and eHealth/Health IT stakeholders, who should collaborate on the following items to enable a standardized international patient summary (IPS) to be in use by 2020:

- 1. Develop and publish an IPS standard to enable the interoperable representation and communication of information about a patient's immunizations, allergies, medications, clinical problems, past operations and implants, building on reusable interoperability assets and tools;
- 2. Work closely with clinician and patient associations in the EU, US, and globally to define, refine, and validate the IPS standard and establish with them a standing governance process under the Joint Initiative Council of SDO Global Health Informatics Standardization to maintain it as new requirements are identified/implemented (e.g. legislation/regulation and learning from the IPS's use);
- 3. Target the IPS as the means for sharing a core set of clinical data for the purpose of emergency or unplanned international patient care, aligning it with other relevant existing standards, and

incorporating where possible the needs of public health and other secondary uses of aggregated health summary data;

4. Work with producers of multi-national terminology systems to publish reliable and quality assured translations of patient summary value sets between relevant languages and cross-mappings between terminology systems; and continue collaboration on eHealth/Health IT standards work in other areas.

2.2 Progress in the implementation of the HHS-EU MoU Roadmap and Action Plan

In the course of the Trillium II project, through cooperation and in broad cooperation with initiatives in Europe, the United States and world wide, we have seen concrete progress in several actions. Numerous workshops have been organized, there have been collaborative activities across SDOs (e.g. alignment CEN/IPS, HL7 IPS, Free set of SNOMED terms), across sectors (Participation in DG ECHO EU Modex exercises), testing events (FHIR Connectathons, IHE Connectathon), innovation events (Hacking Health, FHIR Developer Days), High level Policy Initiatives (European Commission, World Health Organization, World Economic Forum). More details on how specific activities supported the 2016 Roadmap action plan are provided in the Appendix.

2.3 The HHS-EU Roadmap Action plan in retrospect

The implementation of the HHS-EU MoU Roadmap 2016 edition has proceeded slower than expected. Although the standards development cycle has been shorted through joint activities between HL7 and CEN, adoption has been slow. This is partly due to a slow down in globalization and the fact that increased efforts and resources are invested locally in European regions, Member States and the Argonaut Initiative for digitization. With respect to the ability to work with data, even though General Data Protection Regulation was enacted a year ago, adoption is still slow. The same holds true for the uptake of the IPS and the alignment of local or grass route summary specifications to global standards.

Considerable effort needs to be invested in education and digital health literacy including capacity building in interoperability standards. Even though tools developed by SDOs have contributed to accelerated standards implementation and interoperability, work is desperately needed so that tools are further improved and the level of communication and collaboration among different stakeholders increases. Despite the significant progress in the implementation of the Action plan achieved under guidance of the European Commission, with the use of input and recommendations of Trillium II, most milestones were achieved with a delay of one or more years. One of the underlying causes for this delay is an overestimation of the readiness of societies and global organizations to engage with the emerging data economy. More work is needed to understand and provide proof of the value of health data and patient summaries, in particular, and deploy these in ways that bring substantial benefits to individual citizens and the society at large. Concrete EU and US recommendations and initiatives around the transformation of health and care are expected to accelerate progress toward these common objectives.

One particularly promising activity is the alignment of the US core data set employed in the Argonaut project with the HL7 FHIR IPS resources. Already, a study has been commissioned by the US HHS ONC and HL7 FHIR Infrastructure WG⁴ to assess the feasibility for alignment and the Trillium II team had the opportunity to contribute to the draft version. In the long term, we hope that the HL7 FHIR IPS data set would serve as the

⁴ Michele Mottini, Argonaut vs. IPS: A Compare and Contrast between Two FHIR Implementation Guides, HL7 Work Group White Paper, HL7 FHIR Infrastructure Work Group, March 2019

baseline for international interoperability and national program would publish differences from that baseline. Realizing this approach would involve significant awareness effort to connect the emerging communities of practice into a Global IPS Community of Practice that facilitates sharing of experience and information, accelerating the practice of interoperability.

In the next sections, we report on specific activities that support open innovations in digital health through the patient summary and prepare the ground for the creation of the global community of practice for digital health innovation through the use of patient summaries. In this respect, the role and influence of the European Commission should be emphasized.

3 IPS-related Policy initiatives linked to open innovation in digital health

3.1 eHealth Stakeholders group – Towards eStandards a roadmap creation framework

The Standards and Interoperability WG (S&I) of the eHealth Stakeholder Group established by the European Commission, comprising of 16 eHealth umbrella organizations⁵, published the report "Towards eStandards". The report based on original work by the eStandards project (www.eStandards.eu), is dedicated to Patient Ambassador Henk Bakker, who suffered the rare disease Sarcoidosis and advocated for digital health tools that empower patients making them the information hub for their health and care team. The presented framework and methodology for the development of eStandards roadmaps aims drive large-scale eHealth deployment and support the digital transformation of how we manage our health and care and how healthcare is delivered.

Four are the elements of the eStandards roadmap framework methodology:

1. Trust and Flow as the basis of well-functioning health systems. Trust and flow are grounded in the acceptance of four key changes that well-functioning European healthcare systems have to embrace:
 - a. Increasing need, expectation, and cost of healthcare resulting from the combined impacts of ageing populations, increased medical competence, and high investment in new medications and medical technologies;
 - b. Changing nature of the doctor patient relationship in which the patient is much more closely involved with his or her care and seen as an active partner in healthcare, demanding that patients have better access to information about their health and the preferred options for care and treatment that are available
 - c. Increased demand for more home based and mobile care that is available 'just in time'
 - d. A pressing need to extend the capacity of the healthcare workforce as the numbers of those remaining in or indeed entering the healthcare workforce reduce.

Thus, an eStandards roadmap should broadly address:

- e. Building, nurturing and maintaining trust in data, including identification of breaches of trust and their rectification

⁵ HL7 International Foundation (lead), CEN/TC 251 Health Informatics (co-lead), CED (Council of European Dentists), COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry), EHTEL (European Health Telematics Association), EPHA (European Public Health Alliance), ESR (European Society of Radiology), GSMA (Groupe Spéciale Mobile Association), I²H²D (The European Institute for Innovation through Health Data), IHE-Europe (Integrating the Healthcare Enterprise Europe), PCHA (Personal Connected Health Alliance), PGEU (Pharmaceutical Group of the European Union), UEHP (European Union of Private Hospitals), VPHi (Virtual Physiological Human Institute), AGE Platform Europe, EFMI (European Federation for medical Informatics)

- f. Facilitating the flow of data in the whole ecosystem of health management - personal wellness and self-care, informal care, formal care (intramural and extramural)
 - g. Supporting health research, development and innovation
 - h. Establishing learning health systems (professional, organisational and individual) and
 - i. Providing evidence public health and prevention.
- 2. eStandards Compass: Respect for perspectives of stakeholders: The roadmap methodology therefore invites those developing or using standards to orient themselves to the unique but interrelated perspectives of the health system, the workforce, the citizens, and the market for digital health solutions. In order for the compass to remain up-to-date, calibrated to global trends and focusing the local needs and issues, there must be opportunities for the creators and end users of the standards to be engaged together with the four perspectives of the compass and balancing the associated dynamics of the dominant perspectives of health system, workforce, citizens, and market.
- 3. eStandards Roadmap Components: reusing eHealth artefacts: The eStandards Roadmap advocates building iteratively refining eHealth standards artefacts and reflecting on how they met the demands of the Refined eHealth European Interoperability Framework (ReEIF).
- 4. Co-creation, Governance and Alignment (CGA model): These elements bring together the stakeholders in the compass and the existing eStandards artefacts mindful of trust and flow requirements to build the actual roadmap with:
 - a. *Co-creation* - adoption of standard sets and tooling for local specification through collaboration of the stakeholders throughout the process - development, deployment, testing, certification and monitoring;
 - b. *Governance* - recognition and referencing of legal and organisational rules in development of a standard, and conversely of the recognition of standards in the development of organisational rules;
 - c. *Alignment* - the ability to remain flexible, to use evidence constructively in order to refine and maintain the co-creation loop as a continuous virtuous circle of alignment between all players in the system, and across standard sets.

3.1.1 Steps in applying the eStandards Roadmap methodology

Step 1: Using the concept of the eStandards Compass of four perspectives, identify the actors from across the healthcare spectrum who may have an interest in the way in which standards-based solutions are used. Develop appropriate ways of educating them about the value of standards and develop suitable ways of collecting and using their needs. The imperative to provide feedback and acknowledgement is crucial, or the well of co-operation may dry up.

Step 2: Assess the Use Cases, Roadmap Components, and standardised artefacts that already exist and critically assess the extent to which they are able to drive trust and flow of data. Anticipate what is needed to move to the next stage and beyond.

Step 3: Once the needs have been identified and the compass points calibrated, develop a co-creation-governance-alignment process to specify the necessary actions to be taken or supported by Standards Developing Organisations working collaboratively with all relevant stakeholders and the main milestones. Tools for co-creation require to look beyond the usual players to identify fields where lessons may be learned and find new ways to draw players together to learn and develop collaboratively. First, examining the validity of the governance frameworks on which an organisation is built and run. If these are no longer fit for purpose, challenge them and seek to adapt rules to fit needs and capacity in dynamic flexible ways. And second,

engage in a constant flow of alignment, where the parties in co-creation are adapted to fit need, and where governance structures are challenged and where new models of alignment can be embraced.

Based on the application of the methodology, a collaborative course can be plotted in the form of a joint programme of actions at the appropriate (local, regional, national, European or global) level. Applying the methodology to a specific area of eStandards development for standards-based eHealth deployment will yield an eStandards Roadmap of actions. The development of the roadmap itself is to be initiated within a wider program of health innovation and real-world benefits for that specific area of health management and healthcare delivery. The actions identified in the eStandards Roadmap will, in turn, be carried out in the context of this wider program, to safeguard the linkage of the eStandards delivered with the support they provide for standards-based eHealth deployment.

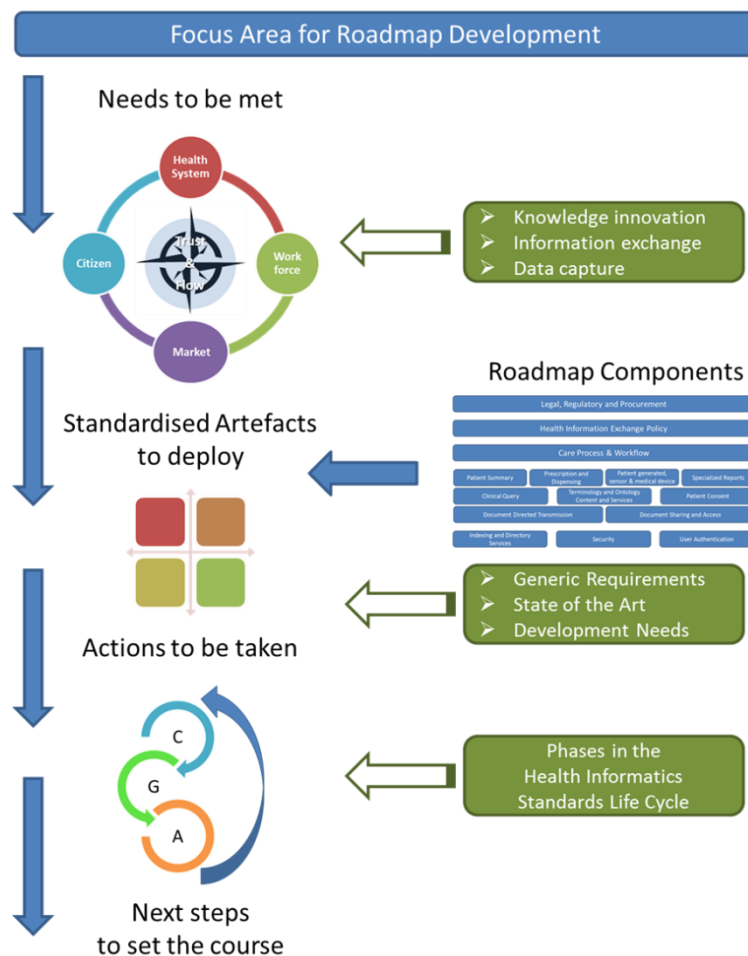


Figure 1: Core parts of the eStandards Methodology.

3.1.2 Recommendations for the application of the eStandards roadmap methodology

Recommendations on where to start with an eStandards roadmap methodology were also offered:

1. Identify keystone projects at a grass-roots level within the Member States that take into account the full range of stakeholders across the eStandards Compass, directly involving citizens as patients and informal caregivers. Such projects will benefit from engaging with the full eStandards life cycle in an entrepreneurial start-up spirit, thus building momentum for eStandards at the operational level of

healthcare provider organisations within Member States, including their vendors, and the citizens and workforce they serve.

2. Support these keystone projects in their use of eStandards through a network of expertise, building upon local collaboration across the national member bodies of Standards Developing Organisations and national eHealth competency centres. Such collaboration will provide a coordinated contribution to local eStandards roadmaps for the benefit of local, regional and European investment.
3. Invest in outreach and education on the eStandards Roadmap Methodology at a national level to strengthen the network of expertise and its linkage to European and global eStandards communities.
4. Consider the role of a European platform representing the eHealth Standards Developing Organisations and national eHealth competency centres, as identified by the eHealth Network. Such a platform could well play a coordinating role as a guardian of the roadmap components and specific standardised artefacts that are identified across the various eStandards Roadmaps for particular focus areas in health management and healthcare delivery across Europe.
5. Engage innovative vendors and users of eHealth solutions to build upon an existing basis of eStandards in action to support the adoption of the eStandards Roadmap approach for the actual delivery of eHealth services and investigate the following concrete topics:
 - a. Join forces between the different Patient Summary initiatives to consider the development of a joint eStandards roadmap for unplanned and emergency care;
 - b. Reach out to projects aimed at advancing integrated care and chronic disease management to help them establish an eStandards roadmap to break down the traditional silos in healthcare delivery;
 - c. Establish an eStandards roadmap in close collaboration with the stakeholders of the Clinical Patient Management System for European Reference Networks for Rare Diseases;
 - d. Advance medication safety and IDMP implementation in eHealth Digital Services Infrastructure (CEF eHDSI) services for ePrescription/eDispensation support with an eStandard roadmap based on EMA regulatory requirements, build in collaboration with national pharmaceutical agencies and vendors of decision support systems for prescription and dispensing of medication;

3.1.3 Relevance to the HHS-EU MoU roadmap with the IPS case study.

For Trillium II, the eStandards roadmap has provided guidance its quest to identify ways to promote the use of patient summaries beyond unplanned care in cross-border settings and respond to information needs of people with concrete health problems. Moreover, the methodology was shared on multiple occasions with the Joint Initiative Council for Global Health Informatics Standardization and to some extent has influenced collaborative efforts. The eStandards methodology has also been adopted by the eHealth Stakeholder Group⁶ and has indirectly influenced a number of national and international initiative e.g. Digital Health Society). As such, it is highly relevant to the future of the HHS-EU MoU roadmap and its aim to address the transformation of health and care with robust and widely adopted interoperability standards.

3.2 eHAction – eHDSI Roadmap for new eHDSI services

eHAction the project supporting the eHealth Network in the implementation of its Multiannual workplan, as part of WP6 Continuity of care, a roadmap is developed to establish new use cases and features for the CEF eHDSI is underway. The methodology is based on the refined eHealth Interoperability Framework (ReEIF) and

⁶ <https://ec.europa.eu/digital-single-market/en/news/new-members-ehealth-stakeholder-group-have-been-selected>

identifies several activities related to interoperability assets that need to be analysed for the use case to be adequately defined.

According to the current (still draft 0.4 version⁷), the evolution of the eHDSI involves new use cases and functionalities that need to be specified and prioritized in appropriate governance processes. At the same time, currently offered services based on existing use cases evolve, are further developed and improved. An approach towards modular components that are efficiently re-usable across multiple use cases, very much like the eStandards artefacts, should be regarded as interoperability assets and be associated with concrete activities not bound to specific use cases but linked to specific layers of the ReEIF.

Identified interoperability assets and related activities are then to be bound to specific targets (use cases, functional requirements, clinical specialties etc.) in order to become measurable “work items” as actionable elements of the roadmap for new eHDSI services. Next, work items need to be assigned to resources and a timeline with concrete milestones, thus delivering the roadmap of a new or revised eHDSI service. An appropriate process of iteratively reviewing the roadmap needs to be considered as part of the evolution and alignment of existing eHDSI services. This process should capture the strategic prioritization, relate it to available resources and include input/feedback from implementers, users, stakeholders, patients etc. An initial list of activities is cited:

- Secure sharing;
- Re-usable use case components;
- Health and Care models;
- Terminology assets;
- Bridge assets to national status quo;
- Review OpenNCP implementation;
- Quality assurance;
- Governance.

3.2.1 Relevance to the HHS-EU MoU Roadmap and the IPS as a case study.

The eHAction roadmap activity is under way at the moment and needs to be validated in the revision of existing services for the cross-border exchange of patient summaries. At first analysis it is detailed enough to facilitate the alignment of global standards and specifications like the CEN IPS, HL7 CDA IPS IG and HL7 FHIR IPS. As such it would influence also global standards and implementation guides through an alignment process.

3.3 Transformation of Health and Care

The three Digital Single Market priorities for the digital transformation of health and care, as outlined in the 2018 European Commission (EC) Communication⁸ are:

1. Citizens’ secure access to and sharing of health data across borders: Several actions of the EC will advance this priority. First EC will review the implementing decision⁹ for the eHealth Network with respect to its governance of the eHDSI and its operational requirements to improve patient access by citizens. Second EC has adopted already a recommendation for the technical specification of the electronic health record exchange format (EHRx) and will monitor implementation of relevant EU

⁷ This version was discussed in the 2nd eHAction roadmap workshop on the 18th of March 2019.

⁸ http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=51628

⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011D0890>

legislation for appropriate data protection safeguards and security of patient data in compliance with the General Data Protection Regulation (GDPR). Third, the EC will support eHDSI to enable new services for the exchange of EHRs and the use of health data for public health and research. Finally, funds from the Connected Europe Facility (CEF), Horizon 2020, and the next multi-annual financial framework will be employed to support implementation in Member States and Regions.

2. Better data to promote research, disease prevention, personalised health and care: Ensuring full compliance with data protection legislation and ethical principles, the EC will set up a mechanism for the voluntary coordination of authorities and other stakeholders to share data and infrastructure for prevention and personalised medicine research, as for example in a network on genomics, other ongoing '-omics' and human cell mapping initiatives. The EC will support development of technical specifications for secure access and cross-border exchange of genomic and other health datasets for research purposes. These technical specifications will facilitate interoperability of relevant registries and databases in support of personalised medicine research. Pilot actions and initiatives for pooling of data and resources across the EU will be funded from CEF and the next multiannual financial program to demonstrate the benefits of advancing research, disease prevention, personalised medicine, health technology assessment, as well as clinical and regulatory decision making.
3. Digital tools for citizen empowerment and person-centred care: This priority will be supported by promoting common principles for validating and certifying health technology, to stimulate demand and supply of digital health technology. Exchange of innovative and best practices, capacity building and technical assistance for health and care authorities on using open standards and interoperable digital solutions to promote health, prevent and manage chronic conditions, empower people and centre care on the person, funded by Horizon 2020, the Structure Reform Support Programme (SRSP) and the 3rd Health Programme, will further stimulate the demand for high quality eHealth solutions. Collaboration with health professional organizations and academia will promote knowledge and skills of citizens, patients, as well as health and care professionals in using digital health solutions. Additional actions will raise awareness about innovative procurement and investment possibilities for digital transformation in public health and healthcare, mobilising relevant EU programmes and financial instruments, the European Investment Bank, investor networks, and possible co-investment approaches under the next multi-annual financial framework.

3.3.1 Relevance to the HHS-EU MoU Roadmap and the IPS as a case study

The communication on the digital transformation of health and care placing empowered and informed citizens at center of their health and care, driving research, health promotion, and personalized health and care, has been a core driver in the development of digital health and the sustainability of health systems globally. The initiatives put forward by the EC have already started to attract interested parties across the Atlantic as well as internationally. These and other initiatives and the promotion of emerging de-facto standards internationally through the CEN/HL7 cooperation can provide the framework for further advancing EU-US and global collaboration on standards and interoperability. The IPS has a prominent role to play in this setting.

3.4 Electronic Health Record Exchange Format (EHRxF)

The EHRxF Recommendation¹⁰ sets up a framework to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the EU. The framework consists of a set of principles to govern access and exchange of EHRs, a set of common technical specifications for the cross-border exchange of data in certain health information domains setting the baseline for the EHRxF, and a process for the further elaboration of the EHRxF, encouraging the Member States (MS) to ensure secure EHR access nationwide.

To ensure secure EHR access nation-wide, MS should ensure high standards for the protection of health data and the security of network and information systems to avoid data breaches and minimize risk of security incidents. Secure electronic Identification means based on eIDAS¹¹ should grant citizens and health professionals online EHR access.

Member States are advised to advance use of EHRs making use of incentives and leveraging appropriate financial instruments, adapting legislation as appropriate. Implementation can be simplified by using CEF eHDSI tools and building blocks and refer to the ReEIF as the common framework for managing interoperability in the eHealth domain. Each MS should set up a national digital health network involving representatives of competent national and regional authorities with clinical and technical competence for digital health matters, the national representative of the eHealth network, supervisory authorities established under Article 51 of the EU Regulation 2016/679 for GDPR¹² and EU Directive 2016/1148 for network and information security¹³. Discussions and consultations with respect to national digital health networks should be shared with the eHealth network and EC.

3.4.1 EHRxF Principles

In establishing the framework for cross-border EHR exchange, MS should ensure that citizens are able to access and choose with who to share their EHRs across borders. Specifically, the following principles are recommended:

1. **Citizen centric by design:** Citizens should be central to the way in which systems are designed implementing the principles of data protection by design and default in compliance to GDPR.
2. **Comprehensiveness and machine-readability:** EHRs should be as comprehensive as possible to support health care services across the Union. Health data in the EHR should be machine-readable, structured and codified to the extent practically possible, to make data interoperable across borders and facilitate their secondary reuse.
3. **Data protection and confidentiality:** EHR systems have to guarantee the confidentiality of personal health data and conform with all aspects of data protection from their design stage onward. The right to transparent information, the right of access and other relevant rights listed in GDPR Chapter III should be fully implemented. Citizens should be able to access their EHRs across borders.
4. **Consent or other lawful basis:** Any processing of health data must be based on the explicit consent of the citizen concerned or on any other lawful basis, in accordance to GDPR Article 6 and 9.
5. **Auditability:** Any processing of health data should be registered and verified for auditing purposes, to keep an accurate record of any processing operation such as EHR access or exchange.

¹⁰ https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=57253;
https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=57254

¹¹ <https://ec.europa.eu/futurium/en/content/eidas-regulation-regulation-eu-ndeg9102014>

¹² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32016R0679>

¹³ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L114>

6. **Security:** Pursuant to the EU GDPR regulation and NIS Directive, implementation of appropriate technical and organisational measures should ensure security of EHR systems and protection against unauthorised or unlawful processing or accidental loss, destruction or damage of health data. Entities exchanging EHRs should ensure the cybersecurity training of personnel dealing with EHRs.
7. **Identification and authentication:** Notified national eIDs supports citizens' cross-border identification and authentication, while assuring the origin and integrity of EHR data through the principle of 'non-repudiation'. Mutual recognition under the eIDAS regulation ensure to citizens of a MS, access to national public services in any other MS with appropriate identification assurance.
8. **Continuity of service:** Continuity and availability of the EHR exchange service is essential to guarantee continuity of care. Any incidents or interruptions that may arise in the course of the use of the service should be promptly addressed in accordance with defined business continuity plans.

3.4.2 Baseline for a European electronic health record exchange format

Member States should take measures to ensure that the following health information domains, as a baseline, are part of an EHRxF for:

1. Patient summary;
2. ePrescription/eDispensation;
3. Laboratory results;
4. Medical imaging and reports;
5. Hospital discharge reports.

The cross-border exchange of information should take place in accordance with the baseline standards, interoperability specifications and the profiles depending on the health information domain as seen in the table below.

Health information domains	Clinical information for cross-border exchange	Content representation for cross-border exchange
Patient Summary	Structured according to the provisions in the "GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 – Patient Summary for unscheduled care" adopted by the eHealth Network on 21 November 20165	Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 26 Level 3 and Level 1 (PDF/A)
ePrescription/eDispensation	Structured according to the provisions in the "GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 – ePrescriptions and eDispensations" adopted by the eHealth Network on 21 November 20168	Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2 Level 3 and Level 1 (PDF7/A)
Laboratory results	Enable cross-border exchange according to the clinical information structure currently used by the sender electronic health record system, while common clinical information structures for cross-border exchange are developed and agreed	For laboratory results, medical imaging reports and hospital discharge reports
Medical imaging and reports		Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2
Hospital discharge reports		Level 3 or Level 1 (PDF7/A) For medical imaging Digital Imaging and Communications in Medicine (DICOM)

Table 1: Health information domains as baseline

3.4.3 Joint Coordination Process for further elaboration of the EHRxF

Further elaboration of the EHRxF in the context of patients' rights to cross-border health care will be done by MS in collaboration with the EC as part of a **joint coordination process** building on the results of existing initiatives of the eHealth Network such as the Common Semantic Strategy task force. MS will engage in discussions and cooperation at Union level with relevant stakeholders, including healthcare professional organisations, national competence centres including those targeting the identification of meaningful medical concepts in each setting, industry actors and patient groups, as well as other Union and national authorities with competence in relevant areas to encourage, and contribute to, an iterative process of further elaborating and adopting a EHRxF. Clinical and technical experts should be involved in work concerning technical and semantic specifications for cross-border exchange of health data, as well as national competence centers targeting the identification of meaningful medical concepts in each setting. The results of these discussions and consultations should be transmitted to the eHealth Network. While the joint coordination process will strive to take forward all MS, individual MS may wish to advance EHR interoperability at a faster speed.

Finally, Members States in the context of the eHealth Network, should cooperate with the Commission and other relevant stakeholders in establishing practical implementation guidelines, sharing good practice and promoting awareness actions for citizens and healthcare providers on the benefits of EHR access and exchange across borders. Pilot projects including research, innovation or deployment actions, such as those supported under the H2020 and CEF Programmes should advance interoperability and raise awareness.

3.4.4 Monitor progress towards interoperability

Members States, in the context of the eHealth Network and in cooperation with the Commission, should monitor progress towards interoperability on the basis of a shared roadmap revised annually, identifying common priorities, tasks, deliverables and milestones. Specifically, MS should share information on measures taken towards adoption of EHRxF specifications and identify common priorities and synergies with national strategies to improve cross-border EHR exchange.

Member States should engage with the Commission and relevant stakeholders to identify and review emerging technological and methodological innovation and identify appropriate steps to achieve progress in the long-term EHR exchange. Assessing of the effects of the Recommendation, MS should cooperate with the EC taking into account their experience and with a view to determine appropriate ways forward.

As such, working towards comprehensive cross-border exchange of electronic health records in a fast changing, connected environment requires regular review of the latest technological and methodological innovations to managing data, including those related to accessing and leveraging of advanced technological infrastructures.

Refinement of EHRxF should consider the possibility offered by resource driven information models (such as Health Level Seven Fast Healthcare Interoperability Resources (HL7 FHIR)). Review of new approaches to interoperability specifications, such as relevant Application Programming Interfaces ('API's) and developments in digital technologies such as artificial intelligence, cloud computing, interaction technologies, high performance computing and cyber security solutions should be carried out. Evolution in other technologies such as distributed ledger technologies may have the potential to build trust amongst citizens and health care organisations provided that they comply with personal data protection rules. The above technologies should be considered with a view to supporting innovation in health care service provision, offering new possibilities to address issues such as health data provenance, and automated integrity assurance.

3.4.5 Relevance to the HHS-EU MoU Roadmap and the IPS as a case study

All the baseline specifications selected for the EHRxP related to global standards. The CEN/IPS cooperation has the potential to influence the alignment of implementation guides for the International Patient Summary. However, period review and alignment of local specifications to global standards and implementation guides is of paramount importance. Taking into consideration work of the ONC Standards advisory and relevant instruments around the world as well as regular meetings to exchange best practices would create a culture of interoperability driven by the soft power of sharing problems and solutions. The discussion and recommendations of Trillium II D5.2 also contribute in the area of alignment and sustainability of component specifications linked to the HL7 FHIR resources that in the future are also part of the HHS standards advisory.

It is imperative to take action in this area, aligning the Argonaut IG to the HL7 FHIR IPS guide, and aligning local, national, or regional implementation guides in ways that would allow to clearly state differences. Further alignment is needed between HL7 CDA (document) and HL7 FHIR Implementation guides and CDA on FHIR may offer an elegant way to support this effort. Already, the HL7 CDA IPS and HL7 FHIR IPS are mostly aligned, and where this was not possible, it is clearly stated.

Morover, there number of HL7 FHIR projects worldwide is rising rapidly. Accounting only for the public projects in one FHIR registry, the Fire.ly simplifier (<https://simplifier.net/>), a public FHIR profile registry are doubling each year to reach 8000 a few days ago. Every day, 10 new FHIR projects are launched in the registry, reaching ~2500 since the beginning of 2019. 26 EU countries are present, at the top are Netherlands, Romania, Germany and France. We hope that the HL7 FHIR Registry will create a one stop registry for all FHIR project, supporting also the adoption of the EHRxP globally.

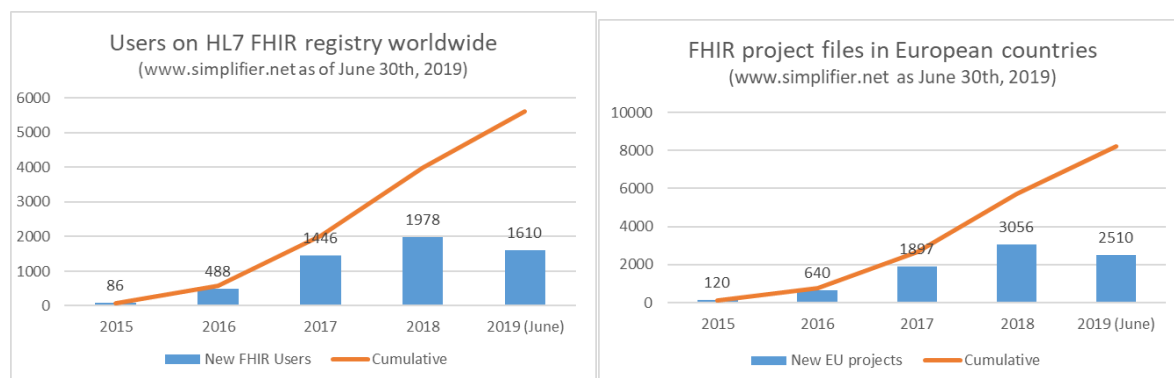


Figure 2: Users of HL7 FHIR doubles every year. 10 new FHIR projects are registered each day in Europe – on the API wave.

3.5 Strengthening Cooperation against vaccine preventable diseases

On December 7, 2018, a European Council adopted a recommendation on strengthened MS cooperation against vaccine-preventable diseases was approved.

The recommendation recognized that vaccination is most powerful and cost-effective public health measure and while vaccination programs are MS responsibility, preventing the spread of epidemics and diseases has a strong cross border dimension. Anti-vaccination activists spread misinformation through social media and fuel misconceptions increasing the risks of communicable diseases. The dialogue with citizens needs to be strengthened to understand and address their legitimate concerns. Health workers across the EU play an important role on vaccination coverage and should offered opportunities of continuous education, and potential cases of low vaccination coverage among health workers needs to be addressed.

The recommendation also recognized variation in MS vaccination schedules with regard to type of vaccines used, number of doses administered, and timing which increase the risk that citizens face when move within the EU. It also recognized that immunization services fail to reach out to the most vulnerable in society and notes that the European Social Fund (ESF) and the European Regional Development Funds (ERDF) offer significant opportunities to the MS to strengthen training of health workers and reinforce capacity for vaccination. Moreover, changes in demographics, citizen mobility and waning immunity require vaccination programs beyond childhood years for health living, active aging, and health system sustainability. MS face frequently vaccine shortages due to lack of coordinated forecasting, making the EU citizens vulnerable to outbreaks of communicable disease. Innovative partnerships and platforms are needed to advance R&D in new vaccines, and improvement of existing ones, as well as in behavioral science research to better understand determinants of vaccine hesitance. The recommendation notes also the mandate (EC regulation 851/2004) of the European Center for Disease Prevention and Control ('ECDC') to foster exchange of best practices and experiences with regards to vaccination programs and strategies, coordinating data collection, validation, analysis, and dissemination in the EU. It also notes the Directive 2001/83/EC and Regulation 726/2004 establishing the European Medicines Agency with the mandate to provide public health authorizing use of safe and effective vaccines.

Council conclusions call for MS to develop joint actions and share best practices on vaccination policies, and to refine immunization registries and information systems to allow for monitoring of vaccination programs. The EC Digital Market Strategy and eHealth action plan 2012-2020 underline the need to prioritize the development of eHealth and big data solutions to enable the transformation of health and care. Directive 2000/54/EC highlights need to protect of workers from risks related to exposure to biological agents offering vaccines to those not previously immunized, while Directive 2010/32/EU says that if the risk assessment reveals risks to the safety and health of workers due to their exposure to biological agents, health workers should be offered vaccination where effective vaccinations exist. EU Decision 1082/2013 on serious cross-border threats to health provides the basis for a voluntary mechanism for the advance purchase of medical countermeasures. The Council conclusions on common values and principles in EU health systems noted the importance of ensuring equity of access to vaccination services regardless of age, social status, or geographical location, in accordance with national and regional immunisation programmes. The resolution of the European Parliament of 19 April 2018 calls for sufficient vaccination of healthcare workers, effective steps against misinformation, and measures for improved access to medicines, and harmonized vaccination schedules in MS.

The Commission supported improved access to essential vaccines in the 77 poorest countries through Gavi, The Vaccine Alliance. Gavi, since its inception in 2000, has contributed to fully immunising 277 million children in the period 2011-2015, with plans to immunise another 300 million children between 2016 and 2020. The World Health Assembly, endorsed the Global Vaccine Action Plan in 2012, so that by 2020 none misses out on vital immunisation and in 2014, WHO Europe adopted the European Vaccine Action Plan 2015-2020. Goal 3 of the 2030 Agenda for Sustainable Development - 'Ensure healthy lives and promote well-being for all at all ages' - underlines the importance of vaccines in protecting people against diseases. The EU and its Member States reaffirm their commitment to protecting everyone's right to enjoy the highest attainable standard of physical and mental health, helping secure access to affordable essential medicines and vaccines for all in the European Consensus on Development 'Our World, Our Dignity, Our Future'. EU-JAVAC the Joint Action on Vaccination, co-funded by the third Programme for the Union's action in the field of health focuses on sharing best practices on national vaccination policies and technical requirements regarding electronic immunisation information systems, vaccine forecasting, prioritisation of vaccine research and development, and research to address vaccine hesitancy. Recognizing the above and the principles of subsidiarity and

proportionality, the recommendation puts forward actions to increase public health security, reduce inequalities and increase the security of vaccine supply.

3.5.1 Recommended Actions for Member States

The recommended actions by 2020 for MS as noted in the council recommendation include:

1. Vaccination plans in accordance to the WHO European Action Plan including provisions for sustainable funding and vaccine supply, a life-course approach to vaccination, capacity to respond to emergency situations, communication and advocacy. 95% vaccination coverage rate with two vaccine doses for the targeted child population, with a view to eliminating measles in the EU.
2. Routine checks of vaccination status and opportunities to vaccinate across the life span in primary care, before starting pre-school, the workplace, community care;
3. Access to national and/or regional vaccination services, leveraging community-based providers and targeted outreach to vulnerable and socially excluded groups to bridge inequalities and close gaps in vaccination coverage;
4. Use of opportunities offered by ESF and ERDF, co-operate with higher educations to support the training and skills development of healthcare workers on vaccine-preventable diseases, vaccinology and immunisation and to reinforce national and regional health infrastructure capacities, including electronic immunisation information systems, in the area of vaccination;
5. Communication activities, training, and awareness-raising on the benefits of vaccination by presenting scientific evidence in understandable form for lay persons, countering misinformation through digital tools and partnerships with civil society and other relevant stakeholders to fight complacency and increase trust in immunisation;
6. Capacity building of health and healthcare institutions to have electronic information on the vaccination status of citizens, for example based on information systems providing reminder functionalities, capturing up-to-date vaccination coverage data across all age groups, and allowing data linkages and exchanges across the healthcare systems;
7. Support for vaccine research and innovation for rapid advancement of new or improved vaccines, and better-informed national or regional vaccination programmes and policies.

3.5.2 Actions for the European Commission in Cooperation with the Member States

1. A European Vaccination Information Sharing (EVIS) system, coordinated by the ECDC: together with national public health authorities should examine feasibility of core EU vaccination schedule and a common vaccination card. Furthermore, with support from National Immunization Technical Advisory Groups (NITAGs), MS should strengthen consistency and transparency in the assessment of national and regional vaccination plans. EU methodologies and data requirements for better monitoring of vaccination coverage across age groups should be designed in collaboration with WHO. The collected data should be shared at EU level (by 2020);
2. A European vaccination information portal, supported by the European Medicines Agency, to provide objective, transparent and updated evidence online on vaccination and vaccines, their benefits and safety, and the pharmacovigilance process. Develop evidence-based information tools and offer guidance to support Member States to fight vaccine hesitancy. Monitor benefits and risks of vaccines and vaccinations, at EU level, including through post-marketing surveillance studies supported by European Medicines Agency in cooperation with ECDC;
3. Develop methodologies and strengthen capacity to assess the relative effectiveness of vaccines and vaccination programs;

4. Apply Union rules on the protection of workers from risks related to exposure to biological agents at work (Directive 2000/54/EC, 2010/32/EU), supporting continuing education of healthcare workers, monitoring their immunisation status and actively offering vaccination where necessary, to ensure adequate levels of patient and healthcare-workers safety;
5. Provide evidence and data, including through the European Schoolnet, to support Member States' efforts to strengthen the aspects related to vaccinology and immunisation in schools;
6. European data warehouse on vaccine needs to strengthen vaccine supply and mitigating risks of shortages: facilitate the voluntary exchange of information on available supplies, possible surpluses and global shortages of essential vaccines; develop mechanism for exchange of vaccine supplies in the event of an outbreak, improving links between supply of and demand for vaccines; explore the feasibility of physical stockpiling and discuss a mechanism to facilitate the stockpiling and availability of vaccines in case of outbreaks, taking into account global shortages of essential vaccines; consider jointly with the vaccine-manufacturing industry possibilities for improving EU manufacturing capacity, ensuring continuity of supply and ensuring diversity of suppliers; explore joint procurement of vaccines or antitoxins to be used in pandemics, unexpected outbreaks and in cases of small vaccine demand; support the EU Official Medicines Control Laboratories network to ensure that vaccines placed on the EU market are of high quality; monitor compliance with the obligation of continuous supply of medicines placed on marketing authorisation holders (Article 81 of Directive 2001/83/EC); facilitate - together with the European Medicines Agency - early dialogue with developers, national policy-makers and regulators in order to support the authorisation of innovative vaccines, including for emerging health threats;
7. EU and national vaccine R&D funding to reinforce existing partnerships and research infrastructures and to establish new ones, including for clinical trials; seek consensus on unmet population needs and agreed priorities for vaccines to inform future vaccine research programmes at national and EU level, including leveraging Coalition for Epidemic Preparedness Innovations ('CEPI') and Global Research Collaboration for Infectious Disease Preparedness ('GloPID-R'); consider investing in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers.

3.5.3 Intended Actions of the European Commission

The EC intends to address issues of insufficient vaccine coverage caused by cross-border movement of people within the EU examining:

1. feasibility of developing a common vaccination card/passport for EU citizens (that takes into account potentially different national vaccination schedules and that is compatible with electronic immunisation information systems and recognised for use across borders, not duplicating work at national level);
2. production of a report on the state of vaccine confidence in the EU, possibly as part of the state of health in the EU, to monitor attitudes to vaccination. Based on that report and taking into account related work by WHO, present guidance to support MS in countering vaccine hesitancy;
3. convening a Coalition for Vaccination to bring together European associations of healthcare workers as well as relevant students' associations, to commit to delivering accurate information to the public;
4. Strengthen the impact of the annual European Immunisation Week by hosting an EU public awareness initiative and supporting Member States' own activities;

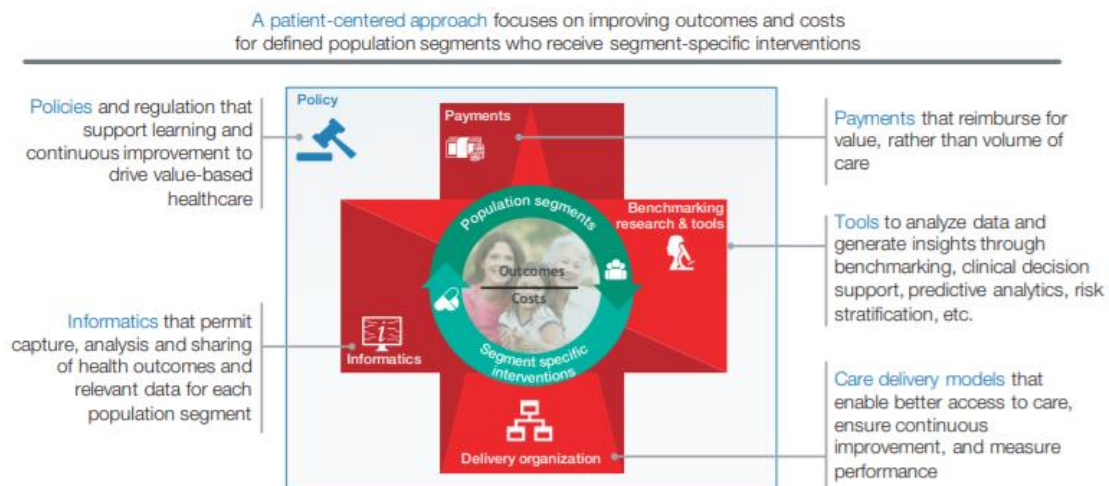
5. Identify barriers to access and support interventions to increase access to vaccination for disadvantaged and socially excluded groups with health mediators and grassroots community networks, in line with national recommendations;
6. Develop guidance to overcome the legal and technical barriers impeding the interoperability of national immunisation information systems enabling the digital transformation of health and care empowering citizens and building a healthier society in accordance to GDPR;
7. Continue to support research and innovation through the EU programmes for the development of safe and effective new vaccines and the optimisation of existing vaccines;
8. Strengthen existing partnerships and collaboration with international actors and initiatives, such as WHO Strategic Advisory Group of Experts on Immunization (SAGE), European Technical Advisory Group of Experts on Immunization (ETAGE), Global Health Security Initiative, Global Health Security Agenda, UNICEF and financing and research initiatives like Gavi, CEPI, GloPID-R and JPIAMR.

3.5.4 Relevance to the HHS-EU MoU Roadmap and the IPS as a case study

Vaccine policies are particularly important for innovation as they address potentially global outbreaks, the fight against antimicrobial resistance, and the agile development of drugs to response quickly to global health risks. In particular, examining the feasibility of a European vaccination card would not be complete if it didn't take into account the CEN/HL7 work on the IPS standard.

3.6 World Economic Forum - Value Based Care and Clinical Informatics Standards Initiative

In a world characterized by an ageing population, more and more people suffering from long-term chronic disease, and ever-increasing healthcare costs, improving healthcare value by delivering better health outcomes to patients at lower costs is a critical imperative. The World Economic Forum's *Value in Healthcare project*, since its launch in July 2016, has laid the foundation for health system transformation by defining the critical components of a value-based health system and by emphasizing the centrality of multi-stakeholder collaboration to achieving value-based system transformation.



Source: BCG analysis

Figure 3: The Value in Healthcare Framework for a Value-Based Health System

In the third and final report of the Value in Healthcare report series¹⁴, three concrete steps were introduced for accelerating the pace of value-based transformation in health systems around the world:

1. A user guide for policymakers and private sectors stakeholders that synthesizes key learnings from efforts around the world to transform health systems towards value;
2. A practical roadmap to guide health informatics standardization, improving our ability to leverage the powerful force of healthcare data towards medical research and real-world evidence, clinical decision-making, patient empowerment and ultimately, improvement in care outcomes;
3. A global coalition to foster collaboration and continue to drive the agenda for value-based health systems.

Stakeholders are in a difficult spot, in that they need to codify and disseminate best practices, develop the global enablers for value-based healthcare, and create new platforms. The World Economic Forum and its partners remain committed to collaborating with key stakeholders to drive value-based transformation of the global health systems.

3.6.1 A five-part agenda with a bill of rights for patient-centered health and care

The Value in Healthcare project assembled an international working group of leading health informatics experts to lead the effort. The working group has developed a five-part agenda for value-based health-informatics standardization. Trillium II was part of this effort represented by Catherine Chronaki.

1. Defining a global vision and person-centric principles

Value-based healthcare puts the patient and value delivered to patients at the very centre of the health system. Therefore, health informatics standards designed to improve healthcare value should also support individuals, placing their health interests at the centre of the standard-setting effort. One effective way to achieve this goal is to develop a digital health bill of rights: A set of foundational principles that inform individual rights of access to personal health data and that govern the use of that health data in clinical decision-making and research. The bill of rights would be endorsed by patient organizations around the world, adopted by stakeholders in the industry, and used to guide any informatics standardization initiatives. Such a **bill of rights might include principles** such as the following:

- Individuals should have access to their health data in a standardized computable format, irrespective of source, through an individualized point of access;
- Individuals should be informed about how their health data is used and, they should be able to provide or withdraw consent for the use of their data;
- Individuals and organizations that have access to their data should be able to use the data to inform care decisions, improve operations, delivering personalized, high-value care advancing research;
- Individuals should be able to provide and share their own outcomes data;
- Individuals and organizations should have access to information based on anonymized health outcomes and other relevant health data, in order to ensure transparency, enhance accountability, enable choices about providers and treatments and improve public health;
- Individuals should be able to grant access to, and meaningfully make use of, their own data.

The advantage of developing a digital health bill of rights is that it will provide a general framework for the creation of health-informatics standards and support the goal of producing truly interoperable informatics systems. International agencies can use these principles to set the global agenda for health-informatics standardization. Patients and patient advocacy groups can use them to create awareness

¹⁴ http://www3.weforum.org/docs/WEF_Value_in_Healthcare_report_2018.pdf

among their constituents and to advocate for governments to include these rights in the legal and policy framework for the national health system. And providers, payers, and pharma, med-tech, health-information and life-science companies can use them to design new informatics initiatives.

Some countries are already building health information systems informed by at least some of these principles. In Estonia, for example, it is a legal requirement for all personal health information to be stored in a machine-readable common format within one to five days of service delivery. The health informatics system links data from different providers and ancillary stakeholders such as ambulance services. Individuals have access to their data through a single point of access. Providers also have access to aggregated data for clinical and research purposes, although patients have the right to restrict access in specific situations. As stakeholders work together to develop the digital health bill of rights, however, it will be important to balance two competing objectives. There is a potential tension between the principle of individuals having control over their data and the principle that data should be available to practitioners, both for the delivery of the best possible care to the individual (for example, in case of emergency) and for benchmarking and research purposes in order to improve healthcare value for the population as a whole. There are effective ways to manage this trade-off to ensure access to individual and aggregated data for healthcare providers and researchers in order to drive improvements in care and in health-system performance.

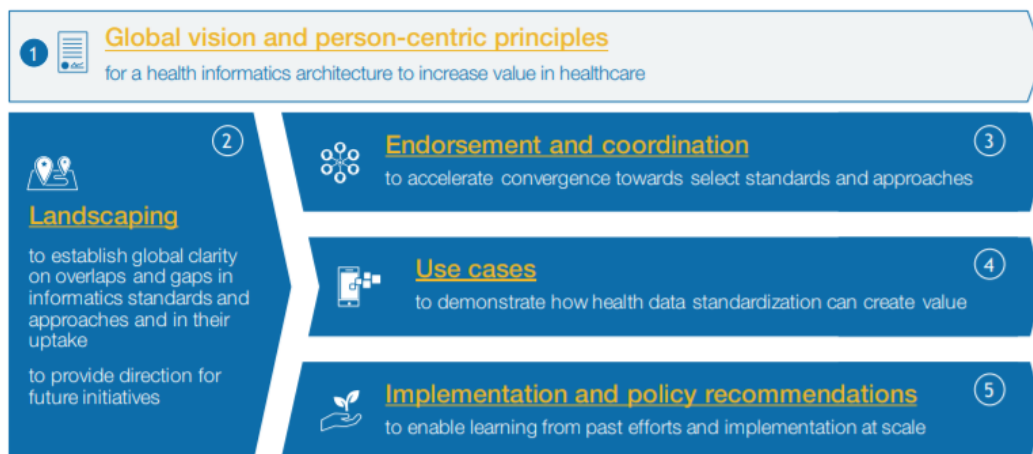


Figure 4: The Value in Healthcare Roadmap for Global Health-Informatics Standardization (source the Value in Healthcare informatics WG).

2. Mapping the standardization landscape: Many initiatives for health informatics standardization are already underway in various countries and regions of the world. Some, for instance, are active efforts to develop relevant standards. Examples include the recently developed Health Level Seven International Fast Healthcare Interoperability Resources (HL7-FHIR) data-model standards, the Clinical Information Modeling Initiative (CIMI) standards for shared implementable clinical information models, and ICHOM's standard sets specifying the outcomes and other metrics to track for a given condition. Other initiatives support the development and implementation of existing standards across the healthcare environment. Examples include:
 - a. The Argonaut Project, a private-sector initiative in the US to refine and spur the adoption of HL7-FHIR standards;

- b. Trillium II, a joint EU-US initiative to accelerate standards development for cross-border exchange of health data, starting with the development of an International Patient Summary standard;
- c. The CommonWell Health Alliance, a US trade association supporting the exchange of health data through the provision of services such as patient enrolment, record location and patient identification and linking;
- d. The European Health Data and Evidence Network (EHDEN), an EU initiative to create a fully interoperable informatics network for European biomedical research.

All of this activity is encouraging, but the growing innovation in the informatics space also makes it critical to develop a clearer picture of the current landscape. In particular, the industry needs to identify overlaps among existing projects as well as any gaps in standards development that need to be addressed in order to capture, map and access the data necessary to enable value-based health systems. For example, there is currently no internationally agreed upon approach to represent patient care plans, including medication regimens, in health information systems; no scalable method for obtaining automated, machine-readable patient consent for data access and usage; no general method for linking health-outcome standard sets to health record data; and only limited taxonomies for representing patient preferences, motivations and values. Thus, mapping the global landscape of ongoing standardization work is critical for defining the priorities of subsequent components of this agenda.

- 3. **Creating governance mechanisms for endorsement and coordination:** Once the current status of existing health-informatics standardization initiatives is captured, the next step will be to create governance mechanisms for endorsing standards and for coordinating their accelerated development and uptake. It is critical that any global governing body assembles a critical mass of global experts to drive industry consensus on the strategic direction for standard setting and development. These experts should include health informatics specialists drawn from both the health technology community and from vital end-user communities that use health data. In some situations, this governing body might even support targeted initiatives to accelerate the development and adoption of endorsed standards. As an illustrative example, consider the HL7-FHIR data-model standards. A targeted project could work with the FHIR and Argonaut communities to speed up the adoption of the FHIR standard in new geographies beyond the US and Australia – for example, by supporting the implementation of the FHIR standard in a subset of “early adopter” countries in the EU and in the Asia-Pacific region. It could also link FHIR to other standard-setting initiatives – for instance, by creating implementation guides for representing ICHOM’s globally endorsed outcome standard sets in FHIR. Finally, the initiative could facilitate input into the ongoing development of the FHIR standard from end-user organizations in the healthcare industry, for example, pharmaceutical or MedTech companies.

4. Developing value-based use-cases: The industry also needs to develop specific use-cases that demonstrate how adoption of informatics standards across multiple health systems can deliver improvements in value to patients and to health systems. Such use-cases should focus on linking the types of data necessary for value-based healthcare – that is, data on population segments (for instance, diagnoses or demographic categories), data on health outcomes (clinician- and patient-reported measures) and data on segment-specific interventions (for example, types of treatment). Most demonstration use-cases will likely fall into one of two categories:

- **Primary uses of data** – for example, developing a holistic view of individual patient data from multiple sources or demonstrating how a clinical-decision support system can be implemented across multiple provider information systems;

- Secondary uses of data – for example, harvesting population-level health data for global benchmarking of risk-adjusted outcomes across health systems or linking data from multiple data sources for the identification of patient segments, predictive analytics or the development of segment-specific treatments.

For an example of one such use-case, the Value in Healthcare project has recently launched an initiative to define a “minimum viable product” for an open-source data model that can facilitate automatic capture and reporting of a standard set of outcomes data from multiple providers without transferring any data tied to a single individual. The model – which, in the initial proof of concept, focuses on cataract disease – will make possible the continuous collection and comparison of outcomes data on an international level (via “remote data-harvest by algorithm”) so that the data can be benchmarked and reported back to the providers on a routine basis. The data model will minimize the need for healthcare organizations to manually compile and report their patient outcomes. The data-model initiative is working in collaboration with the ICHOM Global Outcomes Benchmarking (GLOBE) program, which aims to provide risk-adjusted, international benchmarks on healthcare outcomes by medical condition. In the domain of cataract disease, the GLOBE initiative has assembled a consortium of over 53 healthcare-provider sites in eight countries that conduct cataract surgeries for some 60,000 patients per year.

5. Providing guidelines for implementation: Important as it is to develop common standards for health informatics, it will be equally important to develop best-practice guides for the implementation and adoption of those standards. In addition to specific technical guidance, there is also a need for policy and organizational guidance on effective implementation for governments and industry stakeholders.

3.6.2 The Global Coalition for Value in Healthcare: A new public private partnership

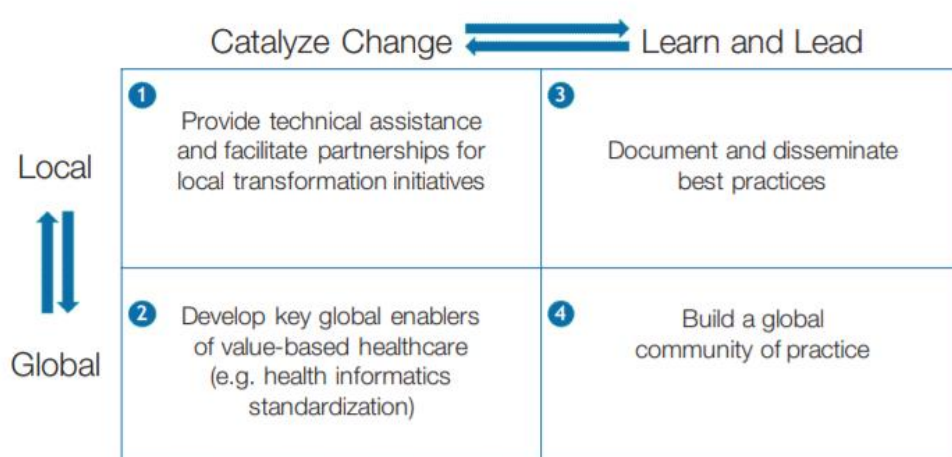
The third initiative launched by the Value in Healthcare project to accelerate the pace of health system transformation is a non-profit, public-private collaboration, initially hosted by the World Economic Forum. Known as the Global Coalition for Value in Healthcare, the organization will continue the work of the Value in Healthcare project after the project’s formal conclusion in January 2019. More information about the Coalition can be found at www.weforum.org/global-coalition-for-value-inhealthcare

The coalition will pursue four strategic priorities at both the local and global levels:

1. Provide technical assistance and facilitate partnerships for local transformation initiatives: The appetite for value-based healthcare is growing around the world. New initiatives are taking shape from the ground up. The coalition will support these and other initiatives aimed at system transformation through the provision of tested methodologies, expert advice and other aspects of technical assistance. For example, it will maintain the User’s Guide to Health System Transformation, mentioned earlier in this report, as a living document, updating and refining it as practitioners’ knowledge about how to undertake effective system transformation develops and expands. The coalition will also facilitate partnerships among stakeholders working within a health system that want to collaborate on new value-based initiatives, and it will partner with local organizations who are championing value-based healthcare.
2. Develop key global enablers of value-based healthcare: Parallel to these local initiatives, there is also considerable activity and experimentation in the design of the global enablers of value-based healthcare. This report describes some of the current initiatives in the domain of health informatics and, as one of its first tasks, the coalition will champion the roadmap for global health-informatics standardization described in the previous section of this report. Over time, the coalition will also undertake thematic explorations on each of the value-based healthcare enablers, for example: value-

based payment; research, benchmarking and decision-support tools; the organization of care delivery; and policy and regulation.

3. Document and disseminate best practices: Value-based healthcare demands iterative learning and continuous improvement. The more that stakeholders do, the more they will learn about what works and what does not. And the more initiatives that are launched, the more important it becomes to identify, document and disseminate best practices and to update existing methodologies. A third activity of the coalition will be to serve as a centre of excellence for the collection and documentation of case studies, techniques and methodologies that practitioners can adapt to their local health systems in order to put value-based healthcare into practice.
4. Build a global community of practice: In the end, the best way to drive momentum for value-based healthcare is through joint, peer-to-peer collaboration in which practitioners and health-system leaders can learn directly from each other about where they have succeeded and where they have failed on their transformation journeys. As the coalition identifies successful local initiatives, contributes to the design of global enablers, and codifies best practices, it will also build a global community of practice to facilitate the systematic sharing of ideas and learning among value-based-healthcare leaders around the world. It will also convene leaders and practitioners in collaboration with its member organizations to accelerate the diffusion of best practices. It is planned to engage with leaders on this community of practice at Davos 2019, where high-priority topics will be identified.



Source: BCG analysis

Figure 5: The Global Coalition for Value in Healthcare Will Engage in Four Critical Activities

3.6.3 Relevance to the HHS-EU MoU Roadmap and the IPS as a case study

The value of the WEF initiative for the Global Coalition for Value in Healthcare is important to the objectives of the HHS-EU MoU roadmap, because it advocates for global standards and cooperation, bridging to the private sector. Moreover, it relates the IPS to value-based care in an approach that engages the International Organization for Clinical Outcomes. According to the recent ICHOM newsletter¹⁵, there has been significant progress in this area: "Mona Khalid, VP of Outcomes Research & Development at ICHOM was invited to discuss measuring, capturing and exchanging outcomes in healthcare during Bruno Bruins, Dutch Minister of

¹⁵ <https://www.ichom.org/2019/07/>

Health recent visit to Boston. In Minister Bruins' session, he reaffirmed the ongoing partnerships between ICHOM and the Ministerie van Volksgezondheid, Welzijn en Sport, Intermountain Healthcare and Boston Consulting Group to harmonise ICHOM data exchange models (see Figure 6). The goal of the Dutch Government is to have outcome indicators available for 50% of the disease burden within five years but without administrative burden. This means that patients and physicians will be able to make shared decisions about the right treatment. The HL7 FHIR IPS linked to Argonaut like accelerators can play a significant role in this space.

Efforts to develop harmonized ICHOM data exchange models are underway

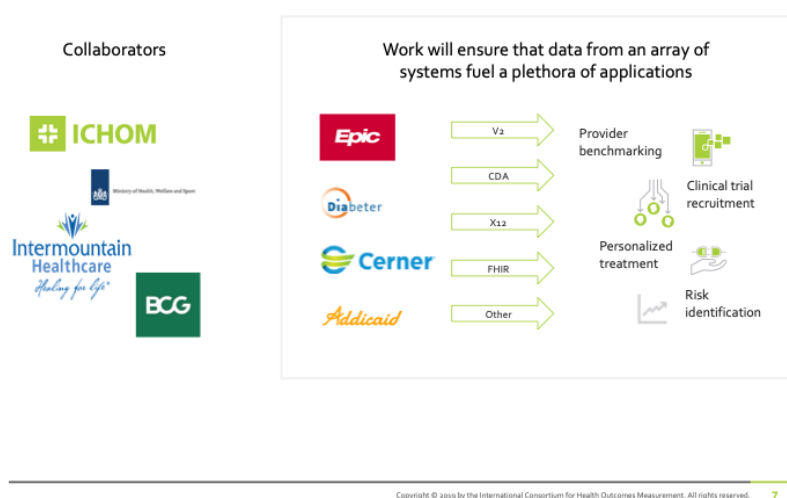


Figure 6: Harmonized ICHOM data exchange models would benefit from the HL7 FHIR IPS resources and the EHRxF, facilitating the move towards value-based care. (figure source <https://www.ichom.org/2019/07/>)

3.7 Mobile Health report to the WHO Assembly 2018

The 71st World Health Organization Assembly that convened in May 2018 was presented with a report by the Director General on "mHealth: Use of appropriate digital technologies for public health"¹⁶ identified a set of priority areas for further consideration in view of 2030 Agenda for Sustainable Development, achieving universal health coverage, and ensuring quality of health services, through increased capacity to implement digital health and mHealth:

The spread of digital technologies and global interconnectedness has a significant potential to accelerate Member States' progress towards achieving universal health coverage, including ensuring access to quality health services. Increasing the capacity of Member States to implement digital health, and in particular:

1. By increasing access to quality health services. A key objective to implementing digital health, and in particular mHealth, is to increase access to health services through the effective and timely sharing of health data, particularly for hard-to-reach populations. For example, the ability to attach specialized devices and sensors, combined with the inherent capability of mobile technologies, increase their reach and power in disease diagnosis, monitoring, management and research. Moreover, information and communication technologies support a variety of critical health system

¹⁶ http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_20-en.pdf

functions by improving the ability to gather, analyse, manage, deliver and exchange information in all areas of health.

2. By increasing access to sexual and reproductive health services; reducing maternal, child and neonatal mortality.
3. By reducing premature mortality from noncommunicable diseases and noncommunicable disease comorbidities. mHealth could help improve awareness of risk factors e.g. use of tobacco, or alcohol, unhealthy diet and lack of physical activity), improve disease diagnosis and tracking, as well as self-care and home care and overall management of chronic conditions.
4. By increasing global health security. Increasing use of the internet and mobile telephones offer new ways to support disease surveillance getting information directly from the public through “crowdsourcing” or community reporting.
5. By increasing the safety and quality of care. Here the report mentions patient summaries: *“The concept of making international patient summary data available through mobile technologies will increase the safety and quality of care by providing secure access to the information needed by the attending physicians at the time of care. This is particularly important in the event of disasters, emergencies and other unplanned care. Mobile technologies allow individuals to have access to their own summary health records and give physicians timely access to these records, which is particularly important when patients seek care outside of their normal care settings.”*
6. By increasing patient, family, and community engagement. The framework on integrated, people-centred health services intends to make health care systems more responsive to people’s needs by putting patients and their families at the centre of health care systems. Thus, delivery systems that support self- and family-driven care through digital, and in particular mHealth are an essential part of the solution.

As a result the 71st World Health Assembly adopted a resolution WHA71.7¹⁷ which adopted resolution WHA71.7 on digital health which recognizes the role that digital technologies can play in achieving progress for sustainable development goals, complementing service delivery: *“(5) to work towards and support interoperability of digital technologies for health by, inter alia, promoting the use of international and open standards as an affordable, effective and easily adaptable solution.”* The resolution further urges member States to assess their use of digital technology for health, to integrate this technology in existing infrastructure, to identify areas where normative guidance and technical assistance are needed, while at the same time disseminating best practices, building capacity for human resources and developing legislation. The resolution also asks the Director-General to develop a global digital health strategy, to provide technical assistance and normative guidance, to develop a repository of information in regulations and evidence on the effects of digital technology, monitoring developments and trends, in collaboration with other UN agencies and other relevant stakeholders to strengthen implementation and generate capacity. Progress report is expected at the Seventy-third World Health Assembly in 2020¹⁸.

3.8 STAIR-AHA platform: Towards a new approach to standards that support active and healthy ageing to engage with users of all age groups

The STAIR-AHA platform created by the EU funded PROGRESSIVE project, recognizes the changing demographics and the fact that older people are an important and growing group of stakeholders some with

¹⁷ http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R7-en.pdf

¹⁸ https://www.southcentre.int/wp-content/uploads/2018/07/PB49_Major-Outcomes-of-the-71st-Session-of-the-World-Health-Assembly-of-WHO_EN.pdf

support needs, with many of them being leaders, caregivers, workers and entrepreneurs aspiring to live in the neighborhoods of the future¹⁹.

The PROGRESSIVE project is encouraging a new way of thinking about standards for ICT related products and services that can support active and healthy ageing. This 'new way' takes account of older people's views and experiences looking at how standards can be developed. It can also be used to improve accessibility, usability and security of those products and services in a context of ageing societies. PROGRESSIVE comprises a multi-stakeholder consortium of 10 partners, including research institutions, national standardization bodies, the European network of older people organizations, and industry associations involved in health and social care.

Standards, regulations, guidelines, specifications and interoperability profiles, can play an important role in making sure products and services respond to the needs and choices of older people. Thus, the role and input of societal stakeholders in the development of standards needs to be strengthened with the reinforced support of organizations representing citizens.

The European standardization frameworks are organized by and for the stakeholders concerned, based either on direct participation (ETSI) or on national representation (CEN and CENELEC) through national standardization bodies. The three European Standards Organizations (ESOs), facilitate the appropriate participation of all relevant stakeholders with community support to consumers' representatives (ANEC), trade unions (ETUC), environmental citizens' organizations (ECOs) as well as small- and medium-sized businesses (SBS). There are noteworthy initiatives at the national level to encourage and facilitate the participation of civil society stakeholders. However, the representativeness of citizen and consumer groups – including in terms of age diversity – remains problematic. AGE Platform Europe, the main European network for non-profit organizations of and for people aged 50+, is also involved in some standardization activities coordinated by ESOs. In addition, AGE works in close collaboration with ANEC, the European consumer voice in standardization, and EDF, the European Disability Forum, on standardization issues. The limited level of inclusion of older people in the standardization process is a missed opportunity. It inhibits efforts to move away from ageist misconceptions of older people's needs and preferences.

The STAIR-AHA platform has developed a statement that outlines recommendations for the need for change in developing standards for active and healthy ageing, which call to standardizers, policy-makers and socio-economic actors involved in standardization to:

- Ensure the compliance of the standards developed with a set of ethical principles which echoes the founding European values of respect and dignity in the EU Charter of Fundamental Rights;
- Raise awareness of the benefits of the inclusion of older people – as experts regarding their own needs and preferences – in standards development;
- Improve the inclusion of a wider range of stakeholders in the standardization process and engage older people's representatives to ensure a better fit of standards with their needs and preferences;
- Make the standardization process accessible in accordance with design-for-all principles to facilitate the participation of civil society representatives (examples of work could encompass user interfaces and built environments that are friendly, accessible and usable).

The statement moves on to recommend first that International, European and national standardization bodies wishing to be relevant for ageing societies in their approaches to standardization should base their work on the following non-exhaustive list of **key ethical tenets**:

- Accessibility and Usability;

¹⁹ <https://www.agileageing.org/page/nof-2019/>

- Affordability;
- Autonomy and Empowerment;
- Beneficence and Non-Maleficence;
- Care, Protection and Support;
- Equality, Equity, Justice;
- Inclusion, Non-Discrimination, Social Impact;
- Interoperability;
- Privacy, Safety, Security.

Second, standardisation processes at all levels should be revised to ensure that they enable the participation of older people's representatives, as a relevant group of stakeholders, to initiatives that concern them most. Standards organizations should be encouraged to reach out to underrepresented groups of citizens and solicit their opinions on relevant questions. Creative user co-production methodologies should be implemented, as a tool to engage all end-users in the standardization process. Specifically, STAIR-AHA recommends promoting the use of the "Guidelines for User Co-production in Standards" developed by the PROGRESSIVE project. Finally, forums of discussion for the dissemination, awareness and discussion of issues related to active and healthy ageing standardization, engaging experts from a broad spectrum of stakeholders' groups such as the CEN-CENELEC STAIR-AHA platform, should be promoted.

3.8.1 Relevance to the HHS-EU MoU Roadmap and the IPS as a case study

The topic of aging societies has been also been addressed in ISO, where a committee, ISO/TC 314 was recently formed.²⁰ The HHS-EU MoU remains silent on the topic of aging societies. However, the recommendations of the STAIR-AHA platform were observed in the report of the eHSG "Towards eStandards". Moving forward the notions of co-production/co-creation, agile governance, and alignment will no doubt underpin transatlantic cooperation on standards and the IPS in particular to guide comprehensive services for the elderly.

3.9 The 2019 Interoperability Standards Advisory

The Interoperability Standards Advisory (ISA) process is used by the Office of the National Coordinator for Health Information Technology (ONC) to coordinate the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the healthcare industry to address specific interoperability needs including, but not limited to, interoperability for clinical, public health, research and administrative purposes. ONC encourages all stakeholders to implement and use the standards and implementation specifications identified in the ISA as applicable to the specific interoperability needs they seek to address. Furthermore, ONC encourages further pilot testing and industry experience to be sought with respect to standards and implementation specifications identified as "emerging" in the ISA. ISA traditionally has reflected recommendations from the Health IT Advisory Committee and its predecessors the HIT Policy Committee and HIT Standards Committee and includes an educational section that helps decode key interoperability terminology. The IPS is close to the Summary Care Record captured in the figure below from page 77 of the ISA edition 2019.

²⁰ <https://www.iso.org/committee/6810883.html>

Summary Care Record

Interoperability Need: Support a Transition of Care or Referral to Another Health Care Provider							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	Yes
Implementation Specification	HL7 Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 - US Realm)	Balloted Draft	Production	●●●●●	Yes	Free	Yes
Emerging Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1	Balloted Draft	Pilot	Feedback requested	Yes	Free	Yes
Emerging Implementation Specification	IHE Patient Care Coordination Technical Framework Supplement 360 Exchange Closed Loop Referral (360X) Rev. 1.1 – Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
Emerging Implementation Specification	NCPDP Specialized Standard	Final	Feedback requested	●○○○○	No	\$	No
Limitations, Dependencies, and Preconditions for Consideration: <ul style="list-style-type: none"> There are several specific document templates within the C-CDA implementation specification. Trading partners will need to ensure that their systems are capable of supporting specific document templates. HL7 provides a C-CDA Example repository which contains a set of example C-CDA files that have undergone a review and vetting process to ensure completeness and rigor. 				Applicable Security Patterns for Consideration: <ul style="list-style-type: none"> Feedback requested. 			

Figure 7: Summary Care Record in the ISA 2019²¹ page 77.

3.9.1 Relevance to the HHS-EU MoU Roadmap and the IPS as a case study

The ISA 2019 includes the Summary Record as presented in the figure directly above. So far it does not include the IPS. Moving forward, perhaps as part of an action in a future edition of the HHS-EU MoU roadmap, we hope that the IPS will be considered to become part of ISA. After the publication of the HL7 FHIR IPS Implementation Guide, both the HL7 CDA and FHIR IPS Implementation Guides will be considered for inclusion in the 2020 ISA edition. In the meantime, the HL7 FHIR IPS specifications will be included in the Inferno testing tool made available by ONC [private communication with Steve Posnack in San Antonio].

3.10 Summary and Outlook

These are exciting times for digital health and the International Patient Summary (IPS) is at the center of developments. Open Innovation is driven by a multitude of policy initiatives driven by regions around the world. Globally, WHO has taken the lead, and patient summaries are likely to be considered among the identified priorities. Telling is the article that appeared in India, announcing adoption of WHA resolution 71.7 in digital health²², where the Health and Family Welfare minister of India Mr. Nadda noted “I’m happy to share that the landmark resolution on #DigitalHealth – initiated by India – was unanimously adopted by the 71st World Health Assembly in Geneva. India received widespread praise for its leadership on this forward-looking agenda” Mr Nadda also said that digital health technology has the potential to support the Universal Health Coverage (UHC) and to improve the accessibility, quality and affordability of healthcare services. To achieve this, Mr Nadda mentioned the programme launched by Indian Prime Minister Mr Narendra Modi called 'Long Live India' (Ayushman Bharat), that consists of health and wellness centres to provide healthcare services and the Prime Ministers' National Health Protection Mission (NHPM).

Initiated in Europe and with increasing worldwide relevance providing input to visible initiatives such as the Joint Initiative Council, Glocal Digital Health Partnership and the Digital Health Society, the eStandards roadmap offers a way to consider the patient summary as a window to a person’s health information in a

²¹ <https://www.healthit.gov/isa/sites/isa/files/inline-files/2019ISAResolutionEdition.pdf>

²² <https://www.opengovasia.com/who-adopts-digital-health-resolution-proposed-by-india/>

number of settings where information is needed for the unplanned or emergency care or people with very specific needs as for children with WHO home based records for immunization and European Vaccination Card. The WEF report on value-based care unveils the importance of the IPS for framing patient outcomes. The ONC ISA shows a potential future for the IPS where it is integrated into national standards and interoperability advisories.

Open Innovation is expected to drive the transformation of health and care services in a connected Europe supported eHDSI service and the EHRxF aligned with International Patient Summary standards.

Moving forward the introduction of the IPS session in the FHIR developer days shows that the interest of the industry picks up. Several FHIR Connectathons, the DataThon in EFMI MIE2018, as well as Hacking Health Athens and evaluation in the EU MODEX Ro disaster management exercise in Romania, certainly helped.

For the future, the intent is that the cycles of co-creation/governance/alignment continue, with trust and flow, and the digital compass balancing the different perspective showing the way for future actions.

4 Open Innovation Initiatives – Implementers and Business Development

4.1 Overview

With the success of the HL7 Fast Healthcare Interoperability Resources (FHIR) standard, which capitalized on open Application Programming Interfaces, we have seen a new generation of tools emerge which capitalize on open innovation, blending the standards development and implementation cycle. As a result, the testing events like the IHE Connectathons organized around completed IHE profiles have evolved to a complex ecosystem of events testing the implementation of standards earlier and focusing more and more on data.

In its efforts to promote open Innovation Initiatives, Trillium II has initiated or actively engaged in a variety of testing initiatives hackathons, datathons, and connectathons providing test servers and tools to assist the overall process. In the following sections, we describe some of these events.

4.2 EFMI MIE2018 DataThon: Emergency admissions - Children with Asthma



The EFMI MIE2018 DataThon was an event promoting the HL7 IPS in the community of the European Federation of Medical Informatics and had a specific focus on Emergency Departments and Asthma cases. It took place over 36 hours in Gothenburg Sweden. WHO monitoring center in Upsala provided access to their resources of adverse events. Participants also had access to Copernicus atmospheric data on pollen, which can influence exacerbations of asthma.

Building on the lessons learned in first European DataThon at IHIC2018 that used Synthea²³, a synthetic health dataset of one Million fictitious but realistic citizens of Massachusetts, US (see relevant article), the MIE2018 DataThon used synthetic census data from Norway, Sweden, Denmark, and Finland. By doing so, it aimed to offer hands-on FHIR training and to validate the use of patient summaries in the health journey of asthma patients. The condition of asthma was selected for several reasons: (a) asthma is the chronic condition that appears earlier in life and has been extensively studied, (b) asthma patients strive to control their asthma with medication and lifestyle choices, (c) environmental conditions can affect status of the asthma, (d) allergies and intolerance are frequently associated with asthma, (e) the DataThon offered the opportunity to explore if and how the International Patient Summary (IPS) could serve the needs of asthma patients and their care givers with a window to the patient's health information linked to data sources across the care continuum.

Reviewing UptoDate (Asthma Management 2015), GINA guidelines (GINA Guidebook 2018), Lung Health in Europe (ERS 2013), and other scientific resources under the guidance of the international clinical advisory board, an asthma patient pathway was created and adjusted with risk factors, to facilitate the creation of the synthetic population.

Following the eStandards methodological approach of Co-creation, Governance, Alignment²⁴, our objective was to validate the International Patient Summary (IPS) Resources that the European Project Trillium II

²³ ¹MITRE Foundation, Synthea, SyntheticMass of realistic but fictional residents of the state of Massachusetts, <https://syntheticmass.mitre.org/about.html>

²⁴ eStandards Roadmap: http://www.estandards-project.eu/eSTANDARDS/assets/File/deliverables/eStandards-D3_5-Roadmap_v1_2a.pdf

released in late 2017²⁵. These resources formed the basis for the HL7 IPS on FHIR specification, which is expected to be approved in May 2019²⁶ aligned with the CEN IPS project²⁷.



Figure 8: The MIE DataThon 2018 - a team effort with more than 12 supporting organizations and projects

The MIE2018 DataThon turned out to be an amazing team effort (see Figure 8). Charlie, Allie, and Harley from Ramsey systems, using public census data and other public statistics on medical consumption, conditions, allergies etc., initiated the creation of 100000 synthetic IPS records using the asthma pathway.

The HL7 FHIR IPS resources did not require major adaptation to fit the needs of asthma patients. Peak flow and Spirometry exams were modeled as observations and DaCHI, DK (team of Prof. Louise Bilenberg Pape-Haugaard, Institutional member of EFMI) provided realistic, but synthetic data. Giorgio Cangioli based on a clinical case provided by Prof Mitch Blair of Imperial U, UK (MOCCHA project – collaborating with Trillium II) created a sample IPS for 14-year old asthmatic patient Danny. The FHIR resources were made available on onFHIR (onFHIR.io), a FHIR server provided by SRDC, TR.

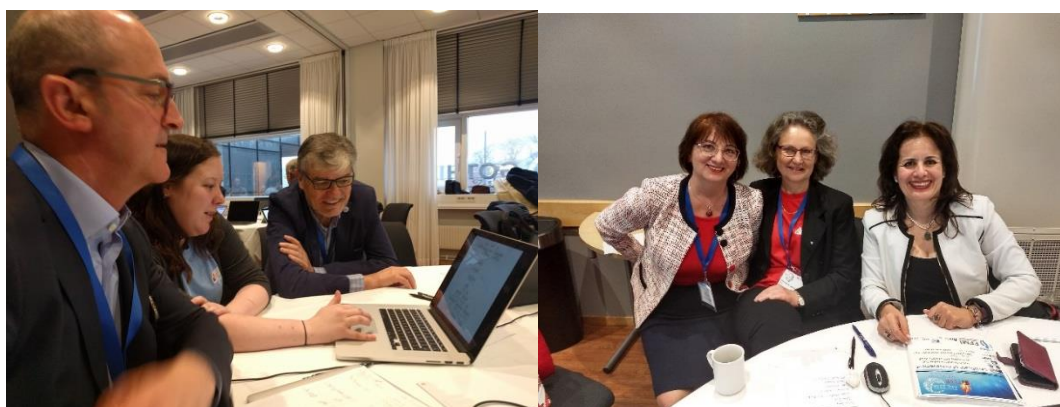


Figure 9: Harley revising the asthma pathway with Luis Garcia-Castrillo chair elect of EUSEM, the European Society for Emergency Medicine (left). Taking a break from the DataThon with EFMI President Elect and Helén Seeman Lodding, Advisory Group Member (right)

Variations of the asthma pathway were developed to focus on different stages junction points of the disease such as exacerbations and emergency admissions, with support from Advisory Group members, Luis Garcia-

²⁵Trillium II resources on simplifier: <https://simplifier.net/TrilliumII/>

²⁶ HL7 FHIR® Implementation Guide: International Patient Summary, Release 1 (PI ID: 1087), Ballot May 2019: <http://hl7.org/fhir/uv/ips/index.html>

²⁷ CEN IPS Project <http://www.ehealth-standards.eu/european-patient-summary-project/>

Castrillo and Andrea Fabbri of EUSEM, the European Society of Emergency Medicine (see Figure 9). The ability to compare the health and economic impact of different health policies in the management of asthma was noted by Joao Fonseca, Pt, but due to time limitations, were not introduced to this edition of the DataThon.



The MIE2018 DataThon offered the challenge of combining the synthetic FHIR IPS resources with web services to (a) pollen levels in atmospheric data from the Copernicus web service²⁸ and (b) medication side effects through VigiAccess²⁹. VigiAccess® web services offer access to aggregated data of suspected medication side effects based on reports of Adverse Drug Reactions (ADRs), so called Individual Case Safety Reports (ICSRs). This data is collected by national drug authorities from over 110 countries and spanning over more than 100,000 different medicinal products to VigiBase®, the global database for ADRs of WHO, maintained by the Uppsala Monitoring Centre.



Figure 10: (left) Ewout Kramer in the HL7 FHIR Tutorial introducing the MIE2018 Datathon ; (right) Giorgio Cangioli presenting the International Patient Summary

The MIE2018 DataThon lasted two and a half days. On Monday April 23, Ewout Kraemer of Fire.ly (Figure 10), offered and energetic half day FHIR training to 25 participants. The full day, Tuesday April 24 was a DataThon working session. After a brief introduction to the rationale and proposed projects by Charlie McCay, Giorgio Cangioli explained the IPS resources and Harley Johnson presented some of the tools available. Then, Jose Teixeira explained the UMC API and the teams chose among proposed projects. Four teams were formed comprising team members from Asia, Americas, Europe, and Middle East. Initially the intent of the MIE2018 DataThon was to attract startups from the Nordic countries interested to experiment with FHIR resources, but marketing efforts was ineffective as the event was in direct competition with the Vitalis exhibition and other MIE2018 events.

4.2.1 Results of the MIE2018 DataThon Competition

The MIE2018 DataThon closing session was hosted by HL7 Sweden on Wednesday April 25, 2018 in the afternoon. Three working solutions were demonstrated, and participants voted for the winner using sli.do.

²⁸ European Air Quality <http://www.regional.atmosphere.copernicus.eu/>

²⁹ VigiAccess <http://www.vigiaccess.org/>

Tom Kane, chair of the EFMI WG LIFOSS on open source software served as rapporteur in the MIE2018 DataThon closing session. Three of the four teams presented their project goals and achievements during the MIE2018 DataThon:

- A team with members from San Francisco, Mozambique, and Taiwan created dashboards to present the status of asthma patients;
- A team from Germany and Qatar explored use of the FHIR IPS resources in the Emergency Department, accessing and updating them;
- A team from Portugal used the UMC API to retrieve further information on medication in the patient summary of child with asthma.

None of the teams had prior knowledge of the data available and their accomplishments were remarkable given the short time available.

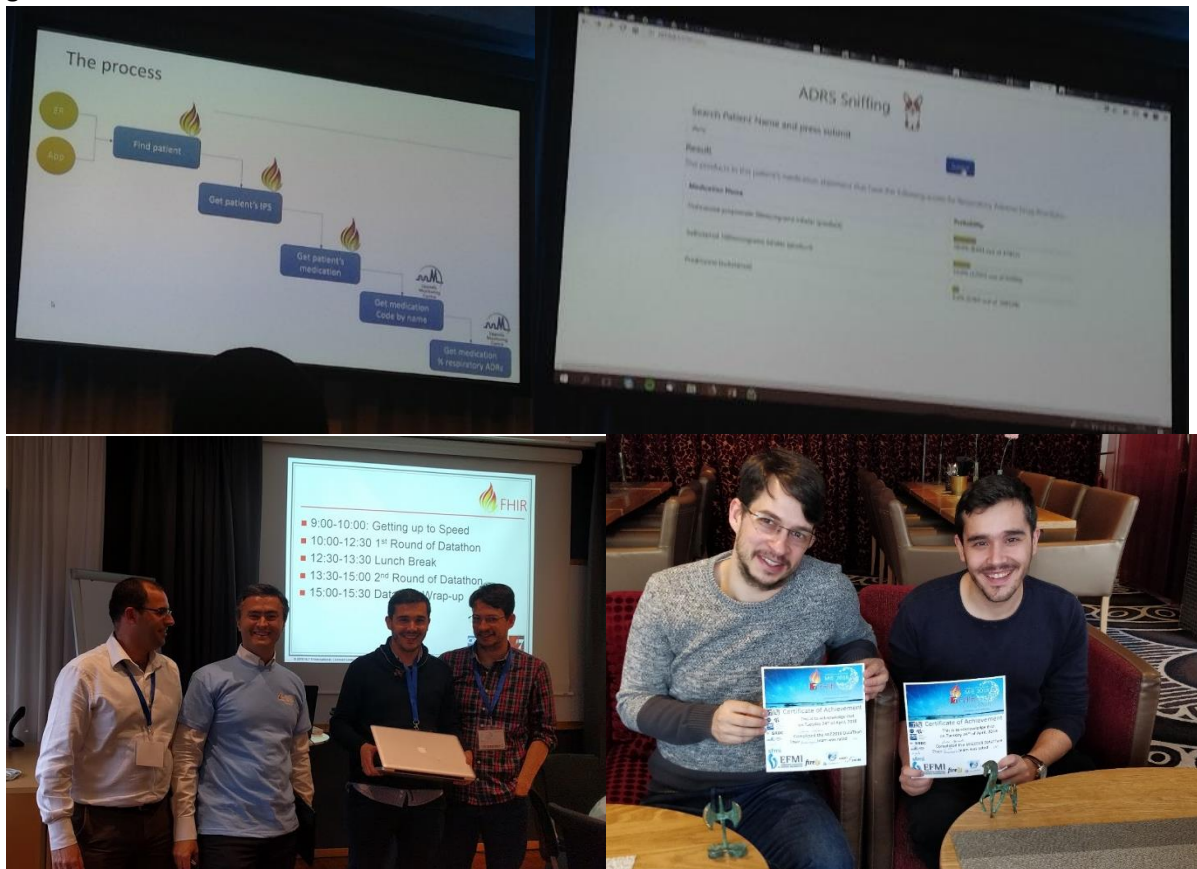


Figure 11: (upper left) Functionality of the winning app for pharmacists combining data from the onFHIR.io server and the Uppsala Monitoring Center for Adverse Events. (Upper Right) ADRS Sniffing app shows adverse events retrieved for Danny's IPS Medication. (Below) Winners of the MIE2018 DataThon, created ADR Sniffing App that combined data from the IPS with Adverse Events retrieved via web services from the WHO Pharmacovigilance Center in Uppsala.

4.2.2 The Winners of the Competition: Patient Summaries and Pharmacovigilance

The winning team, Duarte Ferreira and João Almeida from Portugal presented a prototype of the ADRS Sniffing App, a health professional app that could be used by pharmacists. They received 15 votes. ADRS Sniffing aims to help healthcare professionals consider possible ADR events. Whether in emergencies, prescriptions assessment or pharmacovigilance causality assessments, this application allows the connection to a patient's active medication and reported respiratory ADRs. This could provide improved clinical decision support to healthcare practitioners taking care of asthma patients. Using the Vigiaccess API, the application retrieves from VigiBase aggregated data about ADRs for each medication prescribed to the patient. Afterwards it

processes the data and displays it in a simple web page, listing the respiratory ADRs found for each medication. Both researchers at project NanoStima@CINTESIS (www.cintesis.eu), João is a pharmacist active in IHE pharmacy, and Duarte is developing integration tools for HLTSYS.pt. The team presented graphically their data flow – the way they captured and used data (*Figure 11* left). Their final product was demonstrated as it would appear on a mobile phone (*Figure 11* upper right).

4.2.3 Second Place Winners: Dashboards

The team in the second place with 10 votes comprised Edson Nunes, David Mugume and Eudson Bambo from Global Programs in Mozambique collaborating with Patric Prado from University of California San Francisco. Global Programs for Research and Training was established in 2016 in Maputo, Mozambique with the goal to enhance data use at all levels of the health system to support data-driven decision making for HIV/AIDS care and treatment focusing on national surveillance systems, health information systems, data quality improvement, and data management and use. Prof. Yi-Ju Tseng from Chang Gung University in Taiwan interested in the FHIR standard joined the team. The team developed dashboards to explore the information offered by the data (*Figure 12*). The web application presented the population of asthma patients along different dimensions as the age distribution of asthma patients, as well as prescriptions of inhalers and emergency hospitalizations over time.



Figure 12: Second Winner developed dashboards to explore the data sets on the onFHIR.io server

4.2.4 Third Place: International Patient Summary in the Emergency Room.

The third team comprising Julian Sass from the Faculty of Health Care, University Hochschule Niederrhein in Krefeld, Germany and Abdelkader Lattab from QCRI, Qatar. Julian does research in Health Information Systems, Semantics and Interoperability, focusing is on HL7 CDA, FHIR, SNOMED CT and LOINC. Abdelkader has been actively involved on processing data in real time using distributed stream computing platforms such as Apache Storm. His work also focuses on building mobile health apps for intervention for weight-loss among children with obesity or weight loss and diabetes.

The aim of Germany/Qatar team was to follow the clinical story of Danny, a young asthmatic patient in the emergency room, where they need to access the IPS and update it with new findings. The tools used was an XML editor and REST client. The team succeeded in accessing and processing the IPS resources in FHIR. Following the story of Danny in the Emergency department, they created an allergy resource and updated IPS medication component with the newly prescribed medications (Figure 13). They found that working with FHIR resources was straightforward and compared very favorably with their prior experience with the HL7 Clinical Document Architecture and the CDISC Operational Data Model formats. The team showed examples of JSON and XML FHIR transactions and spent the day learning the technical details of FHIR IPS. They are very interested in implementing FHIR in future projects in Qatar and Germany and felt that the DataThon provided a unique hands-on training opportunity.



Figure 13: The team in the third place simulated a situation where the IPS components are updated in the Emergency Department.

4.2.5 Panel Discussion and Takeaways

The closing panel of the MIE2018 DataThon brought members of the Advisory board to stage to discuss key takeaways with the MIE2018 DataThon participants and to identify next steps: Prof. Rianne Oostenbrink, MD of Erasmus U, Netherlands, Doug Frisma, MD of AMIA, US, Petter Hurlen, MD, Secretary of IMIA Board, Akershus University Hospital, Norway, Russell Leftwich, MD, Member of HL7 International Board, Helén Seeman Lodding, MD, Member of HL7 Sweden Board, and Alfred Winter of Leipzig U, Secretary of the EFMI board joined the stage (see Figure 14). The panel and participants agreed that strong points of the MIE2018 DataThon was how it allowed participants to leverage public health dashboards, information to care givers, and links to other databases. Participants noted that the input from clinicians on the meaning of data during the DataThon was essential.



Figure 14: The closing panelists for the MIE2018 DataThon.

Regarding key takeaways from the event and thoughts for improvements of future events, several suggestions were put forward:

1. HL7 FHIR DataThons provide an excellent opportunity to educate on interoperability standards taking a hands-on approach and demonstrating innovative ideas centered around health data;
2. The MIE2018 DataThon was appreciated for its focus on data standards and that was contrasted to the objectives of hackathons or connectathons. The DataThon encouraged people to think about diverse sources of data imagining how to use data creatively shared or accessed from different healthcare stakeholders (e.g. UMC Pharmacovigilance data), shifting thinking from technical connectivity issues to health policy, evidence-based design of health services, etc.;
3. The focus on specific clinical settings, i.e. pharmacy, by the winning team that designed a tool of potential value to pharmacists assembling data from different sources, was welcomed;
4. Participants suggested that data and resources made available to potential participants before the start of the DataThon, would give them more time to experiment and familiarize themselves with the data;
5. Panelists discussed the challenges related to data quality, how to overcome issues of data collection and curation, and the need for de-identified datasets to enrich the synthetic data sets. Getting the balanced right between focus on a concrete problem to solve with appropriate data sets and a more open-ended DataThon where participants explore a wide area of interest, is critical. Panelists shared that it may take one week to design a data case study idea, and then 6 months to aggregate and clean the data before the idea can be explored;
6. Developing a shared synthetic data resource to which future DataThons would contribute data sets and project ideas would further enrich future DataThons building human capital and advancing knowledge;
7. DataThons offer the setting to explore questions of infrastructure, data provenance, information governance, security and privacy. “With HL7 FHIR, technical interoperability is the least of our problems”, noted one of the clinical advisory group members.

4.2.6 Next Steps

The MIE2018 Datathon was undoubtedly a success offering total FHIR immersion, connecting health data resources in FHIR to Pharmacovigilance data from the Upsala Monitoring Center, and validating the IPS concept for chronic patients suffering from asthma, being admitted to the emergency room. Several improvements were noted and ideas for the next DataThons have been proposed, which aims to bring researchers, standard developers and entrepreneurs together. We are all excited with the idea of DataThons look forward to sharing lessons learned to ensure that future events best cater to the participants’ interests and skills, making DataThon events productive and effective, to build-up standards competencies and advance health data literacy.

4.3 HL7 FHIR Connectathon Baltimore September 2018 – Disaster management

The HL7 FHIR Connectathon in Baltimore served as a remote testing environment for the EU-Modex Ro exercise. Two HL7 FHIR servers provided by Trillium partners Gnomon and SRDC served HL7 IPS samples that corresponded to specific patient cases selected from the database of stories of disaster victims. The specific scenarios tested involved: (a) eHealthPass developed by Gnomon Informatics; (b) Patient Careplan developed by SRDC in the frame of C3Cloud project; (c) European Mobile Field Hospital (EUMFH) developed by the University of Leibniz. Interoperability testing involved retrieving, updating and (re)rendering patient summaries from the two available FHIR servers. Even though, the teams participating in the Connectathon

were separated by several time zones, being located in Baltimore (US), Leibniz (Germany), Ankara (Turkey) and Thessaloniki (Greece), the Connectathon run smoothly and raised awareness about the IPS standard and its application in disaster medicine among a multinational audience. In this sense, it strengthened EU/US cooperation and raised attention about potential gaps with US CORE and the Argonaut specification (see related section above). As a result, a gap analysis is underway funded by the US Office of the National Coordinator.

4.4 HACKING HEALTH Athens

Hacking health took place in February 2019 in Athens. It was the first Hacking Health to provide HL7 IPS resources and ask the community to create applications based on the IPS. It was also the first event to address directly the community of innovators and entrepreneurs. In addition, to the test servers, this event offered to contestants also access to the SNOMED free set.

Just like the MIE2018 DataThon participants were young and entrepreneurial. The main difference was that the participants in this event received as part of the award entrepreneurial coaching.

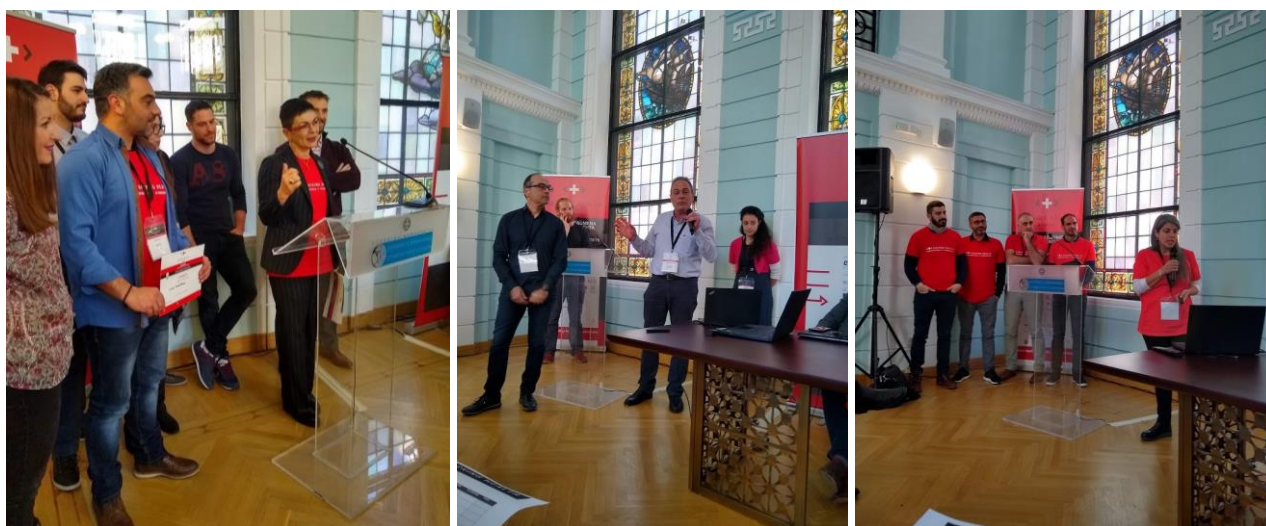


Figure 15: Winners of the Hacking Health Athens Awards (from left to right 3rd, 2nd, 1st)

In preparation for Hacking Health Athens, Trillium organized a webinar to educate the participants of the Hackathon about the HL7 FHIR IPS standard and the tools available to implementers. The webinar was organized together with the eHealth forum and the startup incubator Thea that also hosted the event.

The recipients of the Hacking Health Athens awards implemented proof of concept applications and delivered a pitch on their value and impact. The organizers provided a marketing team that helped the teams prepare their pitch. The first and the third winner looked into the use of the IPS in emergencies. The first winner addressed management of emergency calls for suspected stroke. The application designed used the IPS with smart scheduling techniques. If strong indications, a CT scan was scheduled in an available diagnostic center to aid the decision whether to apply thrombolysis treatment before arrival to the hospital.

The second winner “My babyCare” offered mothers an application to review the vaccination schedule of the kids along with reminders. A mother with multiple kids would see all the kids in one unified interface. A large maternity hospital led this effort.

The third prize supported the community with volunteer rescuers that would respond to emergency calls by fellow citizens in the ambulance was taking long time to arrive. The patient summary was used to match the patient with appropriate rescuer.

4.5 Summary: Power of developers and FHIR movement

HL7 FHIR and the power of APIs has initiated a creative storm and a plethora of APIs in the digital health Ecosystem. Testing events are no longer purely testing technical protocols. Legal, Semantic, Organization, and Business aspects are entangled in open innovation that takes place even before the standard becomes normative. Through Trillium II, EU and the US entities have participated in a variety of testing events that advance interoperability, accelerate development, and promote consistent use of the HL7 FHIR IPS.

5 Open Innovation: Standards Developing Organizations

Collaboration agreements of HL7 and CEN (2017) and synergies between the CEN IPS project, Trillium II, eHAction and eHDSI building on the relevant agreement, have stimulated and maintained a spirit of open innovation that just like the Argonauts initiative accelerated development and adoption of the HL7 FHIR IPS.

5.1 Open innovation in patient summary standards³⁰

Standardization is another form of agreement but deploys a formal consensus process. It definitely takes much longer than putting together a set of preferences for 'my ideal PS', which exacerbates the confusion and hinders interoperability.

The Standardization consensus process, however, does imply the existence of multiple, serious stakeholders. Not surprising, there are a number of concurrent activities, moving in different speeds, pursuing a similar goal in the PS environment in which observers noted that it proved difficult to establish an IPS because of the constantly changing situation.

Fortunately, whilst difficult, it is not as bad as that. Through active, joint participation, three of the four major activities are under the leadership of the Standards Development Organizations (SDOs) and are mutually beneficial and compatible (see Figure 16):

The JIC Patient Summary Standards Set (PSSS) is not intended to be a standard in its own right; it is an informative output that is intended to inform the stakeholders about existing or developing standards in the PS space. By contrast, HL7's IPS and CEN's IPS (the IPS Projects) are intended to be normative and relatively narrow in focus, taking on board relevant detail from the PSSS and contributing to the PSSS content as the IPS Projects develop the formal standards. Furthermore, the IPS Projects are actively working together to produce a single compatible solution based on CEN/HL7 agreement made at the Oslo workshop organized by Trillium Bridge 1 back in 2016. The fourth project is the eHealth Digital Service Infrastructure (eHDSI) initiative for cross-border health data exchange, which builds directly on the outputs of the epSOS pilot with a view of providing implementations for European MS by 2019.

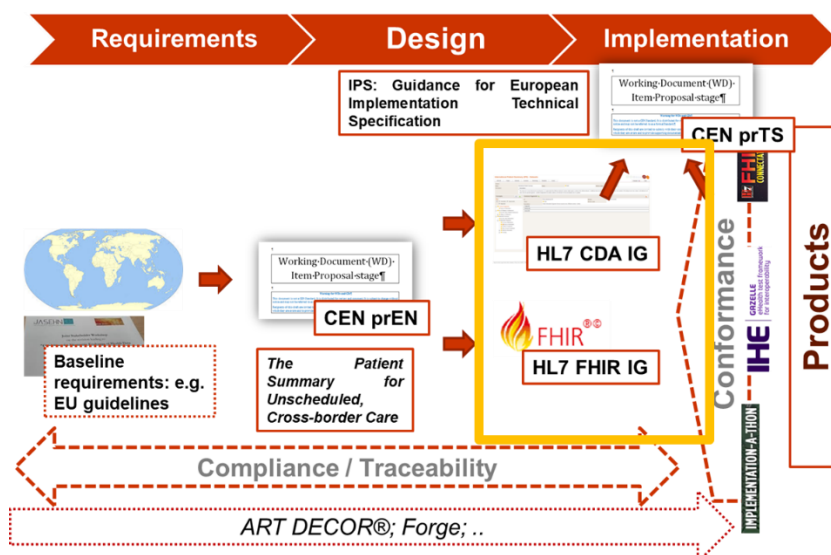


Figure 16: The IPS world of standards

³⁰ This section is based on an excerpt from an article by Stephen Kay authored for the HL7 Europe Newsletter 2018.

All four initiatives rely heavily on the guidelines for a PS dataset, version 2 being published by the European eHealth Network (eHN) in November 2016. This fact goes a long way to support the harmonization efforts of CEN TC 251 and HL7.

The CEN IPS project has produced two standards; the first being a domain model for the IPS focused on the use case of cross-border unscheduled care, and the second, a Technical Specification (TS), which will offer specific guidance for IPS implementation within the European context.

The first, EN 17269, specifies “the core dataset for a patient summary document that supports continuity of care for a person and coordination of healthcare”. It also contains the conformance rules that have to be applied to a derived model in order to comply with this standard. Joint participation has enabled a consistent approach with HL7 and eHDSI, and 17269 provides a means of deriving conformant implementations.

EN 17269 does not overstate or undervalue its contribution, i.e., “due to its nature therefore, readers should be aware that the compliance with this standard doesn’t imply automatic technical interoperability; this result, enabled by this standard, can be reached with the conformity to standards indicated in the associated technical specifications.” An underlying standard (ISO 13940, Systems of Concepts for the Continuity of Care, 2016) underpins the given IPS scenario providing concepts and terms to support the goal of interoperability. The accompanying CEN TS will provide practical examples, showing how other standards (e.g., CDA, 13606 and FHIR representations) may use the prEN 17269 IPS to achieve technical and eventually semantic interoperability for the IPS.

Both specifications were voted positively by the national member bodies of CEN.

The HL7 IPS project will deliver two implementation guides (IG) specifying how the IPS core dataset can be represented through the HL7 CDA R2 and the HL7 FHIR standards.

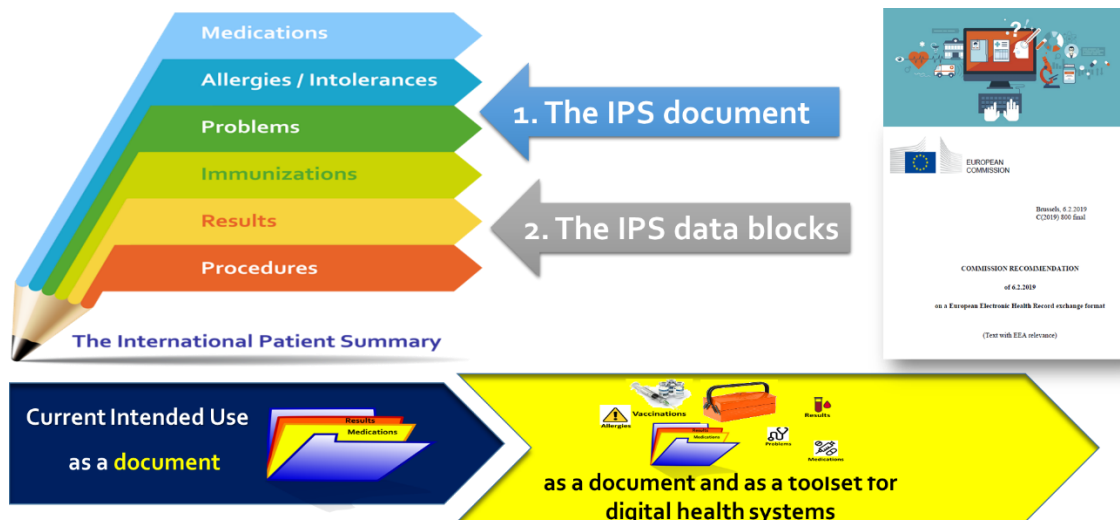


Figure 17: Patient summary both as a document and a set of resources or data blocks can go beyond the exchange of patient summaries across the Atlantic to reusable components that can support the adoption of the EHR exchange format.

The first guide (the IPS CDA IG) has been already successfully balloted and it has been published as Standard for Trial Use (STU) in 2018. This guide defines a set of CDA templates built on pre-existing CDA templates (HL7 C-CDA CCD (Continuity of Care Document); IHE PCC (Patient care Coordination); eHDSI, formerly known as epSOS) to be used for building an IPS document. These templates have been specified and published in

ART DECOR® (<https://art-decor.org/art-decor/decor-project--hl7ips->) to facilitate the templates' formalization and reuse.

The FHIR IPS implementation guide – based on FHIR R4 - has successfully passed the STU ballot (January 2019 HL7 ballot cycle) (<http://hl7.org/fhir/uv/ips/history.html>). The same conceptual content in both the CDA R2 and FHIR specifications, i.e. the IPS core dataset, has been used.

Both the guides share the same design principles in order to facilitate the alignment between CDA and FHIR implementations, without however attempting to provide or require capability for automatic transformation of instances from one standard to the other. Both guides provide support for multi-languages translations; give a strong attention to implementers; and specify the building blocks (CDA templates; FHIR profiles) used for creating an IPS document. Even if the intended use of these “building blocks” is the IPS document; there is a growing interest in looking at them as a library to be reused in other situations, as investigated for example by the European Trillium II project (<https://trillium2.eu/>).

5.2 Argonaut Project



The Argonaut Project is an implementation community driven by the private sector comprising leading technology vendors and provider organizations to accelerate the use of FHIR and OAuth in health care information exchange³¹. The purpose of the Argonaut Project is to rapidly develop a first-generation FHIR-based API and Core Data Services specification to enable expanded information sharing for

electronic health records and other health information technology based on Internet standards and architectural patterns and styles. This effort follows on recommendations from the Joint HIT Standards and Policy Committee's JASON Task Force Report³², the MITRE JASON Reports of 2013³³ and 2014³⁴, and the 2010 PCAST Report.

Code for the Argonaut specific use cases is available in GitHub.³⁵ Argonaut brings closer the digital health industry and the health care provider community to jointly develop specifications based on HL7 FHIR.

Use cases for 2018-19 of the Argonaut project are:

- 1) Clinical Notes: offering guidance on creating and accessing Clinical Notes;
- 2) R4: Update Argonaut Data Query DSTU2 IG to FHIR Version R4. The Argonaut experience dictates robust implementation guides that require real implementation and testing. For this project, the Argonaut Data Query DSTU2 IG will be update to FHIR Version R4 with the goal of having consistency among implementers to meet the USCDI requirements. Includes adoption and testing of US Core R4 resources; adding Encounters and Clinical Notes and consideration of adding “write” capability for a subset of the resources;

³¹<https://www.hl7.org/documentcenter/public/calendarofevents/himss/2018/The%20Argonaut%20Project%20and%20HL7%20FHIR.pdf>

³²JASON Task Force final Reprt

http://www.healthit.gov/facas/sites/faca/files/Joint_HIT_JTF%20Final%20Report%20v2_2014-10-15.pdf

³³ A Robust Health Data Infrastructure https://www.healthit.gov/sites/default/files/ptp13-700hhs_white.pdf

³⁴Data for Individual Health: <https://fas.org/irp/agency/dod/jason/data-health.pdf>

³⁵ <https://github.com/argonautproject>

6 Recommendations for the Future of the EU-US Roadmap

When the first roadmap to operationalize the EU/US MoU on cooperation in the eHealth standards came about, it was about the community. Almost 10 years later the political environment has changed, but collaboration continues.

Considering recommendations based on the experience gained so far in the Trillium II project, these are the main points:

1. Keep on working with open innovation in fora and events (such as datathons, hackathons, DevDays, and connectathons), where we focus on designing solutions for data utilization and interoperability, providing structured feedback to policy guidance and standards evolution.
2. Invest on joint educational and development tools and data resources that can be reused making standards adoption easy.
3. Build communities of practice in which you can share your experience good or bad. Organize joint events and try to understand the legislation around the work to buy in standards and improve procurement.
4. Get back to basics: get the basic parts of the patient summary right with communication, sharing of experiences, data and tools. Working on very concrete and “simple” projects, discussing IPS data visualization, linking, and extensions among clinicians and technical experts.
5. Get the IPS circle bigger through engagement and association with highly visible global initiatives e.g. Global Digital Health Partnership, marketing IPS in a language that can be understood in the respective communities^{36,37}.
6. Make sure major policy initiatives are globally aligned, especially when it involves the API’s for major Electronic Health Record Systems. The US ISA and CDI initiatives can play an important role here, just as the European eHDSI and EHRxF. Extend this to other continents.
7. Collaborative efforts of SDOs (JIC, HL7, CEN and SNOMED), national/regional initiatives and international projects (epSOS/eHDSI continuum, ONC, Argonaut, and Trillium) have shown it is possible to come to international agreements regarding the use and standards used for health data.

³⁶ Health topic at the Global Entrepreneurship Summit <https://www.ges2019.org/ges-2019-at-a-glance/program>

³⁷ StartUp Health <https://www.startuphealth.com/>

7 Ethics Review

The International Patient Summary (IPS) must be sensitive with patient social information like for example psychiatric or substance abuse treatment for not to be used for patient stigma and classification. It must be mandatory, that patients must know that their information will be used in the IPS and what information is shared inside IPS. For this purpose, is necessary to establish an optimal mechanism to inform patients with sufficient guarantees that they are aware of what information will be shared in the IPS.

Therefore, all patients included in the IPS must sign an informed consent to ensure that they are aware that their data will be distributed in the IPS.

It is important to maintain privacy and confidentiality because:

- patients are concerned about the stigma and discrimination associated with their personal conditions (HIV, psychiatric diseases etc.).
- patients must to know that, they can select who has access to their clinical information.
- an IPS with strong privacy mechanisms will promote public confidence and trust in health care services.

It must be also, ensured that the clinical staff who access the IPS, will not use the information for fraudulent purposes. Therefore, anyone who accesses the IPS must comply with the confidentiality criteria established for each country or region involved in IPS

8 Appendix: Progress in the implementation of the HHS-EU MoU Roadmap and Action Plan

The table below presents the list of actions provisioned in the HHS-EU MoU roadmap and its status, at the time of this writing.

International Interoperability Work-stream		
Action	Planned Outcome/Deliverable and Provisional Date	Actual Outcome
Conduct outreach through SDOs such as HL7 and organize EU/US IPS workshops for patient advocacy groups, SDOs, and physician and health informatics and emergency associations	Organize workshops with key stakeholders through SDOs (Fall/Autumn 2016)	Many international workshops, focus groups, discussions, and testing events were organized; follow-up project proposals to refine the notion of IPS for specific citizen or patient needs.
Develop a governance process for IPS updates with the JIC for global SDO health informatics standardization. Deliver draft versions of information structures and associated value sets for IPS components	Draft IPS documents through SDOs (Winter 2016-2017)	Collaborative activities HL7 CEN IHE; under CEN IPS contract; under eHaction IG (see Trillium II, D5.2)
Assess the use of SNOMED CT to express clinical problems and procedures in the IPS	SNOMED CT assessment report (Spring 2017)	Yes (ASSESS-CT project); SNOMED Free set of terms for use in the IPS announced Feb 14, 2019 at HIMSS conference.
Share findings with the clinical research and pharma community as well as patient safety and clinical communities	Present initial findings at the EU-US Conference (Spring 2017)	Multiple times and occasions most recently in Oct 2018; upcoming in FHIR Developer Days; HL7 WG meetings; Speaking engagements.
Seek endorsement for the social value of the IPS effort with global organizations e.g. WHO, United Nations	List of endorsements (Spring 2017)	Several efforts; meetings workshops; Patient Summary mentioned in the WHO Report on We plan to begin engaging with leaders on this at the WHO Assembly 2018 , see forthcoming section in this report.
Initiate pilots to test the use of the IPS, including assessment of alignment between EU and US use of IHE XCPD/XCA profiles.	Pilots testing and demonstrating the use of the IPS (Fall/Autumn 2017)	Disaster Management Exercise EU-Modex Ro 2018; IHE Europe Connectathon 2019; FHIR Connectathon Baltimore 2018, Montreal 2019
Deliver IPS training material for eHealth/Health IT stakeholders, especially caregivers and patients	IPS training material for eHealth/Health IT (Fall/Autumn 2017)	Hacking Health Athens 2019, webinar, material in many languages, not specifically for patients or caregivers, presentations of IPS in multiple languages available at the Trillium II web site.
Investigate possible IPS extensions for public health, registries, rare & chronic diseases	List of IPS extensions (Fall/Autumn 2017)	Cooperation with other large projects and associations: FrailSafe (elderly), 3DCloud (chronic care); EUMFH (disaster medicine); MOCHA (children, registries, EU vaccination card)
Identify synergies with the Interoperability and Workforce Development Work-streams	Better integration between the 3 work-streams	Participation in joint workshops